State of California—Health and Human Services Agency
California Department of Health Services

SANDRA SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

May 14, 2007

Dear Healing Arts Board Executive Officer:

In December 2006, the California Department of Health Services (CDHS) undertook a major healthcare surge initiative to help California's healthcare system prepare for a major disaster. CDHS entered into a contract with PricewaterhouseCoopers (PwC) to carry out an aggressive six-month project to develop the following deliverables:

- A standards and guidelines manual that addresses the existing statutes and regulations that currently govern the standards of care, and identifies those that may be flexed or waived during a declared emergency;
- Operational tools that will guide healthcare planners in the adoption and implementation of new temporary standards; and
- A training curriculum to support the planning and preparation for optimal surge response.

A number of Boards have participated in this project and we want to extend our sincere gratitude to you for your participation and for making this project a priority.

As part of the deliverables for this project, a key issue to be addressed is that of licensed healthcare professionals' scope of practice and the extent to which it may be expanded, or flexed, in response to a declared emergency. The purpose of this letter is to seek your advice on what services healthcare practitioners licensed by your Board are allowed to provide outside their "normal" scope of practice. For example, we are aware that the Pharmacy Board has outlined a set of guidelines that identifies the flexed scope of practice for pharmacists during a declared emergency (See enclosure: Pharmacy Practice Act – Business & Professions Code 4052.1, 4052.2).

Our specific questions are:

- What flexibility in the usual scope of practice does your Board allow during emergencies?
- Are there requirements for supervisory oversight of the professionals licensed by your Board? (For example, current law limits a physician to supervise no more than two physician assistants at any time.) What changes to supervisory oversight requirements are modified/waived during an emergency?

- Are these policies or procedures documented in written form? If not, we would like to discuss with you how to incorporate them into the Standards and Guidelines Manual that will serve as a reference tool, identifying what may be flexed or modified under emergency situations.

- Has any planning or thinking been done around allowing individuals who are not currently licensed by the respective California Board, but have the ability and expertise to perform some or all of the necessary services licensed by such board, to practice during emergencies? (For example, the Respiratory Care Board might consider allowing paramedics to operate ventilators during a catastrophic event; and what planning advice can you provide on allowing students to practice, what services should they be authorized to provide, and under what level of supervision?)

Please forward any available information to Mia Toribio, the PwC staff lead for this area. Mia can be reached at maria.carmina.c.toribio@us.pwc.com, or (310) 938-9590.

If you have questions on this or would like to talk with one of CDHS' Surge Team, please contact Ted Selby at tselby@dhs.ca.gov or (916) 650-6416.

Thank you in advance for your assistance in this aspect of this important project.

Sincerely,

Elisabeth H. Lyman
Deputy Director
Public Health Emergency Preparedness

Enclosure

Pharmacy Practice Act – Business & Professions Code 4052.1, 4052.2

4052.1.
(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

4052.2.
(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and
respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.
(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.
(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.
(2) Demonstrated clinical experience in direct patient care delivery.

Under a declared emergency, the pharmacy board has the authority to waive the application of the act if it will aid in the protection of public health or the provision of patient care. (Business & Professions Code 4062 (b))

NABP Emergency Response Materials

newsletter

National Association of Boards of Pharmacy®

May 2007 / Volume 36 Number 5

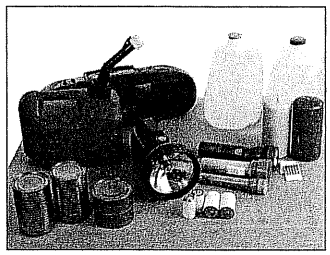
Task Force Offers Recommendations and Guidebook to Help Boards Prepare for Emergencies

When New Orleans residents fled their homes during the onslaught of Hurricane Katrina, grabbing their medication was not the first thing on their minds. Once they made it to a modicum of safety, however, people found themselves without their maintenance medications, insulin, asthma inhalers, and other prescription necessities.

Furthermore, the wreckage and lack of clean water and proper sanitation contributed to illness and injury requiring additional prescription medications such as antibiotics. Hospitals in neighboring regions were overloaded, and not a pharmacy was operable within a 50-mile radius.

Pharmacists from around the country headed to New Orleans to lend a hand, but what to do, where to obtain the needed medications, and how to distribute them safely and without proper records or documentation was far from clear. Many volunteers also had trouble getting through security to assist in restricted areas. Pharmacies and companies that shipped in medications and supplies had a hard time getting the materials to where they were needed, and then getting reimbursed for the provisions they provided.

In an effort to assist the boards of pharmacy to prepare for an emergency situation such as Hurricane Katrina wrought, the NABP Task Force on Emergency Preparedness, Response, and the US Drug Distribution System issued recommendations to the NABP Executive Committee on how state boards of pharmacy, and to a lesser degree, pharmacists, can prepare for disasters. The recommendations were subsequently approved by the NABP Executive Committee and provided to the state boards of pharmacy. The task force was composed of state board members, pharmacy



In an effort to better prepare the boards of pharmacy for an emergency situation such as Hurricane Katrina wrought, the Task Force on Emergency Preparedness, Response, and the US Drug Distribution System has issued recommendations and created a guide to provide direction.

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Emergency Preparedness

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stakeholders, federal and state agency disaster stakeholders, and a liaison from the NABP Executive Committee. The task force developed "Emergency and Disaster Preparedness and Response Planning: A Guide for Boards of Pharmacy" to serve as a resource for the boards.

The **first** recommendation of the task force is that the NABP Executive Committee approve the guide for distribution to member boards of pharmacy to maximize their ability to efficiently respond to an emergency or disaster.

The task force further recommends several amendments to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* addressing disaster or emergency situations. One amendment addresses how boards of pharmacy can work with the governor's office or appropriate state official/office to waive certain laws and rules in the event of a declared state of emergency, when necessary to protect the public health, safety, or welfare of their citizens. Examples include allowing prescription filling when medication vials or patient information is unobtainable and/or processing and temporarily recognizing nonresident pharmacist licensure.

Another amendment assigns the pharmacist-in-charge (PIC) responsibility for developing a procedure for the operation of the pharmacy, to the extent that it can be safely and effectively operated and can safely store and dispense drugs, in the event of a disaster or emergency. The revised language also assigns the PIC responsibility for reporting to the board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of the occurrence.

The task force also recommends several amendments allowing for special provisions during a public health emergency. For example, in such circumstances, a pharmacist may dispense a prescription drug pursuant to an emergency prescription drug order without prescriber authorization; nonresident pharmacists may dispense prescription drugs; pharmacies located in declared disaster areas, nonresident pharmacists, and nonresident pharmacies may temporarily locate or relocate to a temporary or mobile pharmacy facility under certain conditions.

The **second** recommendation addresses task force members' finding that the information concerning emergency preparedness and response at the board level is "severely lacking." Based on this observation, the task force advises the boards to educate their licensees about statutes, regulations, and policies pertaining to emergency preparedness and response. The task force further recommends that, in addition to their Web sites, the boards use newsletters and e-mail notifications to convey policies and procedures, including those related to the licensure or recognition of nonresident licensees, emergency refill dispensing provisions, and temporary pharmacy facilities. Additionally, the task force advises the boards to provide a means for verification of licensure online, which can be vital to emergency or disaster response efforts.

Third, the task force advises the boards of pharmacy and NABP to work with other national pharmacy professional organizations to promote the role of pharmacists as "first responders" in emergency situations, and that they educate state and federal agencies about the role of pharmacists in emergency preparedness and response. First responders, according to Homeland Security Presidential Directive-8, are responsible for the protection and preservation of life, property, evidence, and the environment in the early stages of an incident. They generally include state and local law enforcement, fire departments, emergency medical personnel, and others who provide immediate support services during

Emergency Preparedness

(continued from page 70)

response and recovery operations.

Fourth, the task force recommends that the boards, with assistance from NABP and other pharmacy professional organizations, collaborate with their respective state emergency management agency and governor's office to provide input and direction in the development of emergency and disaster-related proclamations, declarations, or emergency orders.

Fifth, the task force recommends that the boards encourage at least one or two staff members directly involved in emergency and disaster response to be educated on the National Incident Management System (NIMS). A product of the Secretary of Homeland Security, NIMS establishes standardized incident management procedures to enable government, private-sector, and nongovernmental organizations to coordinate response actions during domestic incidents.

The **sixth** recommendation of the task force addresses the difficulties that some would-be responders had in gaining access to the areas in need of services. To ameliorate this problem, the task force advises NABP to work with state and federal authorities to develop a uniform pharmacist identification card, or national ID, providing all necessary credentials and information to allow pharmacists interested in servicing disaster areas access to those areas. Task force members noted that, in areas affected by Hurricane Katrina, access was limited to some areas, and some who wanted to help had difficulty getting to areas in need of services.

Seventh, the task force advises the NABP Executive Committee to consider allowing NABP to offer additional emergency and disaster-related services to the boards of pharmacy, including emergency communications, Web site hosting, emergency declarations monitoring, secure electronic record storage and retrieval, and real-time licensure/registration information maintenance and distribution. The task force further recommends that, if these services are provided, the boards of pharmacy and NABP establish memorandums of understanding allowing NABP to serve as an agent of each board of pharmacy for the provision of designated services, should the board be unable to provide them as a result of an emergency or disaster. The task force also advises that the boards provide copies of all emergency and disaster plans to NABP.

The **eighth** task force recommendation addresses the sometimes contradictory demands of providing needed care to victims while also complying with state and federal laws, including those pertaining to dispensing controlled substances. In recognition of this problem, the task force advises NABP to urge the US Drug Enforcement Administration to develop rules to allow for the emergency dispensing of controlled substances and the shipping of controlled substances to temporary pharmacies established in an emergency situation.

The **ninth** task force recommendation addresses the economic and administrative challenges that pharmacies, pharmacists, wholesale distributors, and other licensed entities have faced as a result of their disaster relief efforts. The task force advises the boards of pharmacy and NABP to request applicable state and federal agencies, such as the Federal Emergency Management Agency, to establish payment and reimbursement mechanisms to ensure prompt and expedient compensation for services provided during an emergency or disaster.

The **10th** recommendation of the task force addresses the shortcomings of the Strategic National Stockpile, a repository of antibiotics, chemical antidotes, antitoxins, life-support medications, airway maintenance supplies, and medical/surgical items. Those assisting in the hurricane relief efforts, however, noted a scarcity of medications to treat common acute illnesses and chronic diseases such as diabetes and hypertension. To better prepare the states for future public health emergencies, the task force advises NABP and other national professional, industry-related, and government entities such as the American Pharmacists Association, the Pharmaceutical Research and Manufacturers of America, and US Food and Drug Administration to consider working together to establish a process and a network for the efficient distribution of medications and supplies in an emergency situation.

The **11th** and final recommendation of the task force addresses the administrative and logistical problems that schools and colleges of pharmacy have faced in the wake of disaster. The task force advises NABP to encourage the American Association of Colleges of Pharmacy to work with its member institutions to ensure that their emergency and disaster plans address concerns such as communication with students and verification of student enrollment. Further, the task force advises NABP to encourage states to license or register student pharmacists as recommended in the NABP *Model Act.*

The task force report and guide are available on the NABP Web site at *www.nabp.net* under News/Press.

Report of the Task Force on Emergency Preparedness, Response, and the US Drug Distribution System

Members Present:

Carl Aron (LA), *Chair*; Michael Brimberry (TX), Ruth Conroy (CA), William Cover (IN), Michael Duteau (NY), David Flashover (NY), Judy Gardner (GA), Dennis Jones (SD), Sara St Angelo (IN), Donald Taylor (MD).

Ex Officio Members Present:

Robert Giacalone, Cardinal Health, Inc; Lisa Robin, Federation of State Medical Boards; Mitch Rothholz, American Pharmacists Association; Walt Slijepcevich, Pfizer, Inc.; Joseph Whaley, Dougherty County Health Department.

Others Present:

Richard A Palombo, *Executive Committee Liaison*; Carmen A. Catizone, Melissa Madigan, Charisse Johnson, Chris Siwik, Gertrude Levine, *NABP staff.*

Introduction:

The Task Force on Emergency Preparedness, Response, and the US Drug Distribution System met on November 16-17, 2006. The appointment of this Task Force was in response to Resolution 102-4-06, Emergency Preparedness, Response, and the US Drug Distribution System, approved by the NABP membership at NABP's 102nd Annual Meeting in San Francisco, CA. This resolution directed NABP continue its efforts to develop a response plan to natural and man-made disasters that affect the US drug distribution system, in collaboration with government agencies, national professional associations, and industry representatives.

Review of the Task Force Charge:

Task Force members reviewed their charge and accepted it as follows:

The charge of this Task Force will be to develop a "Model Emergency Disaster Preparedness and Response Plan" that will serve as a vital resource for the boards. In order to complete the Task Force charge, members will be asked to:

1. Examine the current and evolving roles of the boards of pharmacy in emergency disaster preparedness and response;
2. Develop a model disaster response plan for use by boards of pharmacy;
3. Identify how NABP can assist the boards of pharmacy in their efforts to implement a disaster response plan; and
4. Recommend ways in which the boards of pharmacy and NABP can collaborate with government, industry, and other stakeholders in emergency disaster preparedness and response efforts.

Recommendations:

After significant discussion of the various issues, including but not limited to the roles of local, state, and federal governments in emergency preparedness and response, the recent roles and challenges faced by the boards of pharmacy as a result of 2005's Hurricanes Katrina and Rita, and the need for coordinated emergency preparedness and response efforts among the boards of pharmacy and the public and private sectors, the Task Force made the following recommendations to the NABP Executive Committee:

Recommendation 1: The Task Force recommends that the NABP Executive Committee approve the Task Force's "Emergency and Disaster Preparedness and Response Planning: A Guide for Boards of Pharmacy" for distribution to member boards of pharmacy to maximize their ability to efficiently respond to an emergency or disaster. The Task Force also recommends that the Model State Pharmacy Act and Model Rules of the National Association of Board of Pharmacy (*Model Act)* be amended with the following language addressing disaster or emergency situations.

The revisions recommended by the Task Force are denoted by underlines and ~~strikethroughs~~.

National Association of Boards of Pharmacy Model State Pharmacy Act

Article II

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Section 201. Designation

The responsibility for enforcement of the provisions of this Act is hereby vested in the Board of Pharmacy. The Board shall have all of the duties, powers, and authority specifically granted by or necessary for the enforcement of this Act, as well as such other duties, powers, and authority as it may be granted from time to time by applicable law. In the event of a declared State of Emergency, the Board may waive the requirements of this Act in order to protect the public health, safety, or welfare of its citizens and to facilitate the provision of Drugs, Devices, and Pharmacist Care services to the public.

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Article III

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Comments

Section 201. Comment

In states where centralized prescription filling or centralized prescription processing are not permitted, states may consider allowing the performance of such activities in a declared State of Emergency.

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Section 303. Comment

See NABP's Model Rules for Public Health Emergencies for language that addresses the temporary recognition of non-resident pharmacist licensure in the case of a declared State of Emergency issued due to a Public Health Emergency.

Model Rules for the Practice of Pharmacy

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Section 2. Personnel.

A. Duties and Responsibilities of the Pharmacist-in-Charge

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(2) The Pharmacist-in-Charge has the following responsibilities:

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(n) Developing a procedure for the operation of the Pharmacy, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed, in the event of a fire, flood, pandemic or other natural or man-made disaster or emergency.

(o) Reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence.

...

Section 2A(2)(n) Comment

States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed Pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed Pharmacy area to accommodate the need to store emergency supplies.

Model Rules for Public Health Emergencies

Section 1. Purpose and Scope

By the provision of these rules by the Board, the primary purpose of the section is to enable Pharmacists and Pharmacies to assist in the management and containment of a Public Health Emergency or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public.

Section 2. Definitions.

(a) "Declared Disaster Areas" are areas designated by the Governor or federal authorities as those that have been adversely affected by a natural or man-made

disaster and require extraordinary measures to provide adequate, safe and effective health care for the affected population.

(b) "Emergency Prescription Drug Order" means a standing Prescription Drug Order issued by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a Public Health Emergency requiring mass Dispensing to expeditiously treat or provide prophylaxis to large numbers of Patients.

(c) "Public Health Emergency" means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or nongovernmental organizations to resolve.

(d) "State of Emergency" means a governmental declaration, usually issued as a result of a Public Health Emergency, that may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

Section 3. Emergency Prescription Drug Order

(A) For the duration of a State of Emergency issued due to a Public Health Emergency, a Pharmacist may Dispense a Prescription Drug pursuant to an Emergency Prescription Drug Order if the Pharmacist:

(1) performs, to the extent possible, a Prospective Drug Regimen Review and Patient Counseling in accordance with these rules;

(2) reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Prescription Drug Order," and files and maintains the record as required by state and federal law.

Section 4. Public Health Emergency Refill Dispensing

(A) For the duration of the State of Emergency issued due to a Public Health Emergency in the affected state and in other states engaged in disaster assistance pursuant to a declaration of the Governor or rule of the Board, a Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty (30) day supply, without Practitioner authorization if:

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Refill Prescription," and maintains the record as required by state and federal law, as well as state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency; and

(3) the Pharmacist informs the patient or the patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Presciber's authorization and that authorization of the Practitioner is required for future refills.

(B) For the duration of the State of Emergency, in an effort to provide patients with the best possible care in light of limited Drug availability and/or limited information on patients' current Drug therapy, a Pharmacist may initiate or modify Drug therapy and Dispense an amount of such Drug to accommodate a patient's health care needs until that patient may be seen by a Practitioner. Pharmacists performing such activities must utilize currently accepted standards of care when initiating or modifying Drug therapy. These activities may be undertaken if:

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates that Drug therapy has been initiated or modified due to a disaster or emergency, and maintains the record as required by state and federal law; and

(3) the Pharmacist informs the patient or the patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

(C) The Practitioner and Pharmacist shall not incur any liability as a result of the performance of these activities in good faith pursuant to this section.

Section 5. Temporary Recognition of Non-Resident Licensure

(A) When the Governor declares a State of Emergency due to a Public Health Emergency:

(1) a Pharmacist not licensed in this State, but currently licensed in another state, may Dispense Prescription Drugs in areas affected by the Declared Disaster during the time that the State of Emergency exists if:

(a) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system; and

(b) the Pharmacist is engaged in a legitimate relief effort.

(2) a Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(a) the Board can verify current registration or licensure in good standing of the Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy

Intern directly with the state or indirectly via a third-party verification system; and

(b) the Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern is engaged in a legitimate relief effort.

(3) a Wholesale Drug Distributor not licensed in this State, but currently licensed in another state, may Distribute Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(a) the Board can verify current licensure in good standing of the Wholesale Drug Distributor directly with the state or indirectly via a third-party verification system; and

(b) the Wholesale Drug Distributor is engaged in a legitimate relief effort.

(4) the temporary recognition of non-resident licensure or registration shall cease with the termination of the State of Emergency.

Section 6. Temporary or Mobile Pharmacy Facilities

(A) Pharmacies located in Declared Disaster Areas, non-resident Pharmacies, and Pharmacies licensed in another state but not licensed in this State, if necessary to provide Pharmacy services during a State of Emergency, may arrange to temporarily locate or relocate to a temporary or mobile Pharmacy facility if such facility:

(1) is under the control and management of the Pharmacist-in Charge or designated supervising Pharmacist;

(2) is located within the Declared Disaster Area or affected areas;

(3) notifies the Board of its location;

(4) ceases the provision of services with the termination of the State of Emergency; and

(5) maintains records in accordance with laws and regulations of the state in which the disaster occurred.

(B) The Board, in accordance with Board rules, shall have the authority to approve or disapprove temporary or mobile Pharmacy facilities and shall make arrangements for appropriate monitoring and inspection of the temporary or mobile Pharmacy facilities on a case by case basis. Approval of temporary or mobile Pharmacy facilities will be based on the need, type, and scope of Public Health Emergency, as well as the ability of the temporary or mobile Pharmacy facilities to comply with state and federal drug law.

(C) A temporary Pharmacy facility wishing to permanently operate at its temporary site must notify the Board in accordance with Article V, Section 503 of these Rules. Mobile Pharmacy facilities may operate only during a State of Emergency and may not be permanently operated.

Comments

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Section 1. Comment

States may consider adding the following, more detailed language, which specifically addresses drug disposal and reporting requirements in the case of an emergency or disaster, to their emergency rules or guidelines:

Disposal of Prescription Drugs in Pharmacies Affected by a Certain Disasters

1. For pharmacies that sustain flood and/or fire damage in the Prescription department, the entire Drug inventory, including Drugs awaiting pick up by patients, becomes unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy.
2. For Pharmacies that experience a loss of power for an extended period of time, the Drug inventory must be evaluated for continued product integrity using USP standards. For example, medications with Labeling requiring storage at "controlled room temperature" must be kept at between 68 degrees and 77 degrees, with brief deviations of between 56 and 86 degrees. Medication inventories found to have been stored outside of USP standards become unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy. For Pharmacies with questions on USP product integrity standards, contact USP at 800/227-8772.

Reporting of Theft or Loss of Controlled Substances During an Emergency or Disaster

1. In circumstances of theft by looting, burglary, etc., where evidence or witnesses indicate the medications were taken by someone, the nearest DEA Diversion Field Office must be notified by telephone, facsimile, or brief written message of the circumstances of the theft immediately upon discovery. In addition, the Pharmacy must complete *DEA Form 106– Report of Theft or Loss of Controlled Substances*, found at www.deadiversion.usdoj.gov, to formally document the actual circumstances of the theft and the quantity of controlled substances involved, once this information has been conclusively determined.
2. In circumstances of damage or where Drugs were irrevocably lost to flooding or other circumstance, such information must be reported on *DEA Form 41 – Registrants Inventory of Drugs Surrendered*, found at www.deadiversion.usdoj.gov.
3. The amount stolen or lost may need to be calculated by taking the most recent controlled substances inventory, adding the amount purchased since that date, then subtracting the amount Dispensed and Distributed since that date. In the absence of a calculated amount, a best estimate should be reported.

Disposal of Prescription Drugs Irrevocably Lost in an Emergency or Disaster

1. Controlled Substances.
   Reverse Distributors, either individually or in concert with other contractors, are equipped to dispose of controlled substances. Contact your primary Distributor for their recommendations for a reverse Distributor or contact a reverse Distributor directly.
2. Contaminated Medical Debris
   Non-controlled substance Prescription Drugs and Devices contaminated with flood water or other contaminants should be disposed of using a medical waste transportation, processing, and disposal system vendor. Such vendors must be licensed by the state.
3. Hazardous Debris

Materials are deemed hazardous if they are ignitable, corrosive, toxic, or reactive. Prescription Drugs considered hazardous include, but are not limited to, epinephrine, nicotine, nitroglycerin, physostigmine, reserpine, selenium sulfide, chloral hydrate, and many chemotherapy agents, such as cyclophosphamide, chlorambucil, and daunomycin. Other hazardous items that might be found in a Pharmacy include paints, varnishes and thinners, alcohol, batteries, mercury thermometers, and blood pressure cuffs. It is recommended that Pharmacies handle all contaminated Prescription medications as hazardous debris and dispose of it using a hazardous waste collection and disposal company. These companies must be licensed by the state.

4. Commercial Waste

Over-the-counter Drugs and other store shelf material may be disposed of in the commercial waste stream.

Section 2(B). Comment

Boards may consider identifying the official who has authority to issue an "Emergency Prescription Drug Order."

Section 3(A)(1). Comment

Although these services are important, in times of a disaster or emergency, it may not be possible to perform a Prospective Drug Review or provide counseling on Dispensed Drugs.

Section 4(A). Comment

Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

Section 4(B)(2). Comment

Boards should be cognizant that state and federal disaster agencies, to ensure continued provision of care during disasters or emergencies, have programs that consider reimbursement requests for medication providers and may request Board assistance in the dispersal of funds. Records of dispensing will likely be needed for possible reimbursement consideration. In addition, records may also be used for post-event evaluation of care.

Section 5(A)(1)(a). Comment

If the information cannot be verified directly by the Board of Pharmacy in which the Non-Resident Pharmacist is licensed, NABP's Clearinghouse may be utilized to verify that a Non-Resident Pharmacist has not had disciplinary action taken against the license.

Section 6(A). Comment

Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure that controlled substances may be delivered to and Dispensed from temporary or mobile Pharmacy facilities.

Background:

With assistance from the US Department of Homeland Security's *Ready Business* Guide, the Georgia Pharmacy Foundation's *An Action Plan for State Pharmacy Associations to Respond to Natural or Man-Made Disaster* (March 1996), and emergency preparedness and response plans submitted by the boards of pharmacy, the Task Force developed the "Emergency and Disaster Preparedness and Response Planning: A Guide for Boards of Pharmacy" (Guide).

The Guide contains, among other items, NABP's "Recommendations for Preparing and Responding to an Emergency or Disaster," a "Model Emergency and Disaster Preparedness Response Plan," and "Model Rules for Public Health Emergencies," as well as emergency and disaster resources provided to boards by NABP.

NABP's "Recommendations for Preparing and Responding to Emergency or Disaster" provide a timeline for the boards of pharmacy to employ in preparing and responding to an event. Its "Early Preparation for an Emergency or Disaster" section directs the boards of pharmacy to work proactively to create emergency and disaster preparedness and response plans, work with the state legislature to enact emergency dispensing and other related provisions, develop rules, and develop a contact list of public and private stakeholders, with whom the board of pharmacy may work with in the case of a disaster. The "Immediate Response to an Emergency or Disaster" section provides a foundation for the board's response in the event of an impending situation, outlining when the board should activate its emergency or disaster plans, make initial contact with various stakeholders crucial to response efforts, and release important information to licensees, the general public, the media, and others. The "Short-Term Response" section addresses the board's response up to 72 hours post the event, directing the board to continue its immediate response activities, while basing further action upon up-to-date information received from, for example, state and federal agencies, or others. Finally, the "Long-Term Response" section addresses the continuing response activities, including, if necessary, efforts to restore board operations, sustain communications with important stakeholders, and provide continuous updates to licensees, the general public, the media, or others.

The "Model Emergency and Disaster Preparedness and Response Plan" consists of six comprehensive sections that form a template to develop or supplement an existing emergency or disaster preparedness and response plan. This Model Plan has sections on Emergency Planning, Maintaining Board of Pharmacy Operations, Communications, Evacuation Planning, Shelter-in-Place Planning, and Protecting Business Resources.

The "Model Rules for Public Health Emergencies," which are intended for incorporation into the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act),* and which are outlined above, provide suggested statutory and/or regulatory language intended to enable pharmacists, pharmacies, and other licensees to assist in the management and containment of a public health emergency or similar crises. The provisions address emergency prescription drug orders, emergency refill dispensing, temporary recognition of non-resident licensure, and temporary or mobile pharmacy facilities.

Finally, the Guide outlines emergency and disaster resources currently provided by NABP to assist boards in their efforts. Currently, NABP offers expedited licensure transfer and verification

services to allow boards to swiftly register and recognize non-resident pharmacists and pharmacy technicians. As indicated in Recommendation No. 7, it is hoped that more services can be offered in the near future.

Recommendation 2: The Task Force recommends that the boards of pharmacy take a proactive approach in educating their licensees on statutes, regulations, and policies pertaining to emergency preparedness and response. As part of these efforts, the Task Force recommends that boards provide a means for the online verification of licensure.

Background:

Task Force members found that information concerning emergency preparedness and response at the board of pharmacy level is severely lacking. Most boards of pharmacy have Web sites that relay extensive information on pharmacy laws, initial licensure and licensure renewal processes, continuing education requirements, and board meetings, but not on board requirements, policies, procedures, or other information concerning emergency or disaster preparedness. It was suggested that, in addition to the board Web site, newsletters and e-mail notifications could be utilized to convey specific policies or procedures, including those related to the licensure or recognition of non-resident licensees, emergency refill dispensing provisions, and temporary pharmacy facilities.

Task Force members emphasized that the ability to verify, online, the licensure of pharmacies, pharmacists, and other licensees, can be vital to emergency or disaster response efforts. This capability, for example, may allow a board to quickly import and assign volunteer licensees from other states to areas where services are needed. Online licensure verification services have other obvious benefits as well. They provide quick and easy information to the public, providing assurance that a pharmacy is properly licensed by the board, and to employers, allowing them to easily verify that an employee is properly licensed and without pending disciplinary actions.

Recommendation 3: The Task Force recommends that boards of pharmacy and NABP, in concert with other national pharmacy professional organizations, work to gain and promote the designation of pharmacists as "first responders," so that they may serve as crucial resources in emergency response efforts. As part of these efforts, the Task Force also recommends that NABP and other pharmacy organizations collaborate to educate state and federal agencies about the role of the pharmacist in emergency preparedness and response.

Background:

According to Homeland Security Presidential Directive-8 (HSPD-8), "first responders" are those individuals who, in the early stages of an incident, are responsible for the protection and preservation of life, property, evidence, and the environment. First responders include emergency response providers as well as emergency management, public health, clinical care, public works, and other skilled support personnel, and state and local law enforcement, fire department, and emergency medical personnel, who provide immediate support services during prevention, response, and recovery operations. First responders are usually the first fleet of human resources to be deployed to bioterrorism attacks, terrorist attacks, catastrophic or natural disasters, and emergencies. First responders may also need to undergo additional education and

training to develop manipulative and problem solving skills necessary for the initial medical evaluation, stabilization, and treatment of victims of emergency illness or trauma.

Pharmacists, given their knowledge base, role in the delivery of medication therapy, and accessibility, are naturally an important resource to be utilized in the event of a disaster or emergency, and particularly as first responders. For example, in the event of an influenza pandemic, pharmacists are likely to be first responders in that they could be utilized in the mass dispensing of prophylactic medications to the general public. The American Pharmacists Association in conjunction with the American Society of Health-System Pharmacists and the National Association of Chain Drug Stores, have taken the initiative to develop a guidance document intended to assist pharmacists in preparing for an influenza pandemic and educate them on the training opportunities and resources, practice support, and planning for emergency medication/vaccine supply and distribution.

The pharmacist's role in emergency preparedness and response has been exemplified by recent incidents. Countless numbers of pharmacists and support personnel inundated regions of the Gulf Coast in late 2005 to provide sorely needed help. Four years prior, on September 11, 2001, pharmacists were also on site in New York City, at the Pentagon, and in rural Pennsylvania. Pharmacists serve with the Medical Reserve Corps, an organized group of medical and public health professionals who serve as volunteers to respond to natural disasters and emergencies, and are commissioned officers of the US Public Health Service. In August 2006, the International Pharmaceutical Federation (FIP) released its statement of professional standards regarding the role of the pharmacist in crises management. This document noted that pharmacists can, among other things, develop guidelines for treatment of casualties and exposed individuals, select medicines and related supplies for national and regional stockpiles; ensure proper packaging, storage, handling, labeling, and dispensing of emergency supplies of medicines, and ensure appropriate deployment of emergency supplies of medicines.

The Task Force members emphasized the need for the profession to collectively promote pharmacists as "first responders" in the interest of serving and protecting the public health. Correspondingly, the Task Force members stressed that with this designation pharmacists should, if needed, undergo additional training, obtain additional certifications (ie, CPR certification, immunization certification, etc), and possess a basic understanding of local, state, and federal emergency response systems. Additionally, first responder pharmacists may need to be appropriately vaccinated per the recommendations of the Centers for Disease Control and Prevention.

Recommendation 4: The Task Force recommends the boards of pharmacy with assistance from NABP and other pharmacy professional organizations collaborate with their respective state emergency management agency and the gubernatorial office to provide input and direction in the development of emergency and disaster related proclamations, declarations, or emergency orders.

Background:

The boards of pharmacy, with assistance from other pharmacy professional organizations, are well-equipped to advise the respective state emergency management agencies and the office of the governor on crafting government declarations, proclamations, or emergency orders that may

affect the statutory and regulatory provisions of the pharmacy practice act or rules. Additionally, boards of pharmacy should proactively work with their state legislature, if necessary, to enact or revise emergency dispensing and other related provisions for future events.

Recommendation 5: The Task Force recommends that boards of pharmacy encourage a minimum of one or two staff members directly involved in emergency and disaster response at minimum be educated on the National Incident Management System (NIMS).

Background:

On February 28, 2003, President Bush issued (HSPD-5), which directed the Secretary of Homeland Security to develop and administer a National Incident Management System (NIMS). NIMS provides a consistent nationwide template to enable all government, private-sector, and nongovernmental organizations to work together during domestic incidents. Specifically, NIMS establishes standardized incident management processes, protocols, and procedures that enable federal, state, tribal, and local responders to effectively and efficiently coordinate and conduct response actions. The Task Force members agreed that board of pharmacy staff, such as compliance/investigator staff, should have a working knowledge and understanding of NIMS.

Operated by the Federal Emergency Management Agency, the Emergency Management Institute (EMI) offers a number of independent study and distant learning programs (at no cost) specifically targeted to meet the emergency management training needs of federal, state, and local governments. For example, independent online Course IS-700 NIMS, An Introduction, takes approximately three hours to complete and explains the purpose, principles, key components, and benefits of NIMS. EMI also offers a number of other courses covering topics such as the Incident Command System, principles of emergency management and planning, effective communication, and basic disaster operations.

Recommendation 6: The Task Force recommends that NABP work with state and federal authorities to develop a uniform pharmacist identification card (national ID) and to ensure that all necessary information is included on the card to allow pharmacists interested in servicing disaster areas access to such areas.

Background:

Task Force members discussed their efforts to assist in areas affected by Hurricane Katrina. Because access to such areas was limited, some had difficultly getting to areas in need of services. It was suggested that a uniform national identification card might provide the appropriate credentials and information to allow access to affected areas.

Recommendation 7: The Task Force recommends to the NABP Executive Committee that it strongly consider the possibility of NABP offering the following additional emergency and disaster-related services to the boards of pharmacy: emergency communications; Web site hosting; emergency declarations monitoring; secure electronic record storage and retrieval; and real-time licensure/registration information maintenance and distribution. Furthermore, the Task Force recommends that if these services are provided, that the boards of pharmacy and NABP establish memorandums of understanding allowing NABP

to serve as an agent of the board of pharmacy for the provision of designated services should the board be unable to provide them as a result of an emergency or disaster. The Task Force further recommends that boards forward all emergency and disaster plans to NABP.

Background:

Recognizing that an emergency or disaster can render a board office inoperable, similar to the events of late 2005 when the Louisiana Board of Pharmacy found this to be the case, the Task Force recommended that the NABP Executive Committee consider expanding NABP's services to include those that may assist boards in restoring crucial board operations. Emergency communications, emergency declaration monitoring, Web site hosting, electronic data storage, and real-time licensure/registration information maintenance and distribution services can be tailored to meet the specific needs of the boards and can prove vital to quickly restoring services.

NABP, utilizing its extensive network of relationships with national organizations, could communicate information to entities on behalf of the affected board(s) of pharmacy. Communication tools could include the NABP Web site, e-mail, telephone, and other means. Realizing that a board's Web site is the primary source of information for licensees and others, and is likely to be the primary source of information to a greater extent in the event of an emergency or disaster, the Task Force recommended that NABP work toward providing services to host the affected board(s) of pharmacy Web site temporarily until the board's servers are restored or replaced. Utilizing information from the Federal Emergency Management Agency and other sources, NABP could also proactively monitor federal and state emergency declarations, executive orders, and other related information and provide that information directly to boards and others as necessary.

The Task Force members also suggested that the NABP Executive Committee consider developing an infrastructure and designate resources to collect and maintain licensure information on pharmacists, technicians, and other persons or entities licensed or registered by the boards to ultimately provide a mechanism for real-time licensure status information. As noted by the Federation of State Medical Boards in its report, *Responding in Times of Need: Katrina and Beyond*, the timely sharing of physician licensure and sanction information by all state medical boards was key in assisting the Louisiana State Medical Board in verifying non-resident licenses and documenting the licensure of Louisiana-based physicians and medical students wishing to transfer to other states. Additionally, FSMB's Federation Credentials Verification Service (FCVS) was particularly helpful. Established in September 1996, FCVS is a permanent repository providing a centralized and uniform process for state medical boards to obtain a physician's core medical credentials (medical education, postgraduate training, examination history, board action history, board certification, and identity). Also maintaining information on physician assistants, this repository of information allows a physician and/or physician assistant to establish a confidential, lifetime professional portfolio with FCVS that can be forwarded, at the physician's request, to a state medical board that has established an agreement with the FCVS, or any hospital, health care, or other entity.

The NABP Clearinghouse primarily contains pharmacist disciplinary information obtained from the boards of pharmacy. Utilized primarily to assist the boards of pharmacy in processing licensure transfer requests, the Task Force members agreed that this database could be expanded

to include "real time" licensure data for pharmacists, pharmacy technicians, and pharmacy interns with information continuously obtained from the boards of pharmacy. In the event of an emergency or disaster, this information can be quickly and easily used to verify licensure of pharmacists and support staff. The enhanced Clearinghouse would also have other advantages: for example, it would provide a secondary electronic back up of licensure data at an off site location. NABP could further provide additional storage for other records as a board requests.

Ultimately, if NABP were to offer these type of services, the Task Force also recommended that the boards of pharmacy and NABP establish memorandums of understanding allowing NABP to serve as an agent for a board of pharmacy for the provision of specific, designated services should the board be unable to provide them as a result of an emergency or disaster.

Further, the Task Force recommended that all boards of pharmacy forward a copy of their emergency or disaster plans to NABP for secondary storage in the event that the plans are inadvertently destroyed.

Recommendation 8: The Task Force recommends that NABP approach the US Drug Enforcement Administration (DEA) and urge them to develop rules to allow for the emergency dispensing of controlled substances and the shipping of controlled substances to temporary pharmacies established as a result of an emergency or disaster.

Background:

In the midst of post-Hurricane Katrina, pharmacies in many states grappled with providing the needed care to victims, while at the same time, complying with various state and federal laws, including those pertaining to the dispensing of controlled substances. Although some states allowed the emergency dispensing of controlled substances, the lack of federal regulations addressing this issue was a valid concern of many pharmacies providing relief assistance. Many boards of pharmacy, also concerned about the compliance of federal laws, contacted DEA for guidance. In turn, DEA, working in conjunction with the boards of pharmacy, did allow, per a temporary policy, the emergency dispensing of controlled substances for hurricane victims. For example, information obtained from the Mississippi Board of Pharmacy Web site indicated that DEA approved dispensing of controlled substances in Schedules II through V in an emergency situation during the period September 1, 2005 through September 30, 2005, for persons displaced by the hurricane.

The Task Force agreed that it was crucial for NABP to urge and work with DEA to develop federal regulations regarding the emergency dispensing of controlled substances. Additionally, the Task Force also suggested that regulations be developed to allow controlled substances to be shipped to emergency or temporary pharmacies, to ensure that such pharmacies are able to receive shipments of controlled substances.

Recommendation 9: Realizing the economic and reimbursement challenges often faced by pharmacies, pharmacists, wholesale distributors, and other licensed entities that assist in emergency and disaster relief efforts, the Task Force recommends that boards of pharmacy and NABP request applicable state and federal agencies (such as the Federal Emergency Management Agency) to establish payment and reimbursement mechanisms to ensure

prompt and expedient compensation for services provided during an emergency or disaster.

Background:

The Task Force members recognized the importance of properly reimbursing pharmacies and other entities that provide emergency and disaster relief-related services. In order to mitigate the financial hardship for entities providing relief efforts, the Task Force recommended that boards of pharmacy and NABP request that applicable state and federal agencies establish mechanisms now so that payment can be provided expediently in the event of a future emergency or disaster.

Without the established payment mechanisms in place, a board of pharmacy may find itself serving as a liaison between pharmacies and other third parties. For example, pursuant to a request of the Louisiana Department of Health and Hospitals (DHH), the Louisiana Board of Pharmacy collected reimbursement claims submitted by pharmacies assisting in relief efforts in the aftermath of Hurricane Katrina. Working with DHH and FEMA, the Louisiana Board of Pharmacy served as an intermediary by swiftly creating processes and forms so that claims could be submitted to the Board, and subsequently to FEMA.

Recommendation 10: The Task Force recommends that NABP and other national professional, industry-related, and governmental entities such as the American Pharmacists Association (APhA), the Pharmaceutical Research and Manufacturers of America (PhRMA), and the US Food and Drug Administration (FDA) consider working together to establish a process and network for the efficient and optimal distribution of drugs.

Background:

Orchestrated by the Centers for Disease Control and Prevention, the Strategic National Stockpile (SNS) is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, airway maintenance supplies, and medical/surgical items. Although the SNS is primarily designed to supplement and re-supply state and local public health agencies in the event of a national emergency, those assisting in relief efforts after the hurricane found the SNS limited in its ability to meet the immediate therapeutic needs of the victims. The SNS medication repository contains medications and supplies that are largely used in treating patients affected by nerve agents, biological pathogens, and chemical agents. The needs of the hurricane victims, however, called for a broader array of medications to treat both common acute illnesses and chronic diseases such as diabetes and hypertension.

Recognizing the limitations of the SNS and the frustration expressed by pharmacies, wholesale distributors, and pharmaceutical manufacturers in ensuring that donated medications ultimately reached disaster victims, the Task Force agreed that perhaps important stakeholders such as the boards of pharmacy, NABP, FDA, APhA, and PhRMA, should work together to establish mechanisms and networks that would facilitate the distribution of medications and supplies in the event of a local or national public health emergency or disaster. Specifically, this network could delineate the coordination systems and processes that the existing drug distribution system, in conjunction with local and state government, would utilize to efficiently and effectively donate, store, and distribute medications and supplies to targeted areas of need.

Recommendation 11: The Task Force recommends that NABP encourage the American Association of College of Pharmacy (AACP) to proactively work with its member schools and colleges of pharmacy to ensure that existing emergency and disaster plans address concerns such as, but not limited to, communication with students and verification of student enrollment. Further, the Task Force recommends that NABP encourage states to license or register student pharmacists as recommended in the NABP *Model Act*.

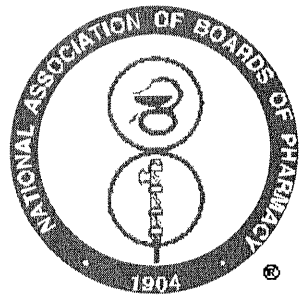
Background:

As a result of Hurricane Katrina, the University of Louisiana at Monroe College of Pharmacy and Xavier University College of Pharmacy were among the colleges of pharmacy most affected. In efforts to assist the 590 pharmacy students displaced from Xavier alone, AACP assisted in the placement of fourth-year students at alternate facilities to complete experiential requirements.

Realizing that many schools and colleges of pharmacy belong to a university system and are not private, stand-alone institutions, the Task Force agreed that NABP should encourage AACP to provide direction and guidance to schools and colleges of pharmacy so that existing emergency and disaster plans address matters such as, but not limited to, communication with students and procedures for verifying student enrollment. For example, in addition to including a Web site page dedicated entirely to emergency preparedness, Xavier University has also implemented toll-free telephone number that would, in the event of an actual emergency, be the official source of information for students, faculty, and staff.

Although the *Accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree* mandate the development of procedures regarding transfer credit and course-waiver policies (Standard 18), the Task Force discussed the challenges experienced by students and schools/colleges of pharmacy wishing to verify and authenticate the enrollment of students temporarily displaced by Hurricane Katrina. These students, who had hoped to continue professional degree courses at other schools of pharmacy, were unable in the immediate hurricane aftermath, to prove their matriculation into a professional degree, which presented obvious challenges to schools that were willing to temporarily accept them. Therefore, the Task Force recommended that NABP urge AACP to work with its member schools/colleges of pharmacy to develop a mechanism by which student enrollment and other information, such as course work completed, could be easily verified and authenticated in a practical time frame.

Along these lines, it was agreed that uniform licensure or registration of student pharmacists by state boards of pharmacy would complement these efforts.



Emergency and Disaster Preparedness and Response Planning: A Guide for Boards of Pharmacy

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Executive Summary

The Task Force on Emergency Preparedness, Response, and the US Drug Distribution System met on November 16-17, 2006. The appointment of this Task Force was in response to Resolution 102-4-06, Emergency Preparedness, Response, and the US Drug Distribution System, approved by the NABP membership at NABP's 102nd Annual Meeting in San Francisco, CA. This resolution recommended that NABP continue its efforts to develop a response plan to natural and man-made disasters that affect the US drug distribution system, in collaboration with government agencies, national professional associations, and industry representatives.

The Task Force was specifically charged with developing a "Model Emergency Disaster Preparedness and Response Plan" that would serve as a vital resource for the Boards. In order to complete this charge, the Task Force members were asked to examine the current and evolving role of the boards of pharmacy in emergency disaster preparedness and response, identify how NABP could assist the boards of pharmacy in their efforts to implement a disaster response plan, and recommend ways in which the boards of pharmacy and NABP can collaborate with government, industry, and other stakeholders in emergency disaster preparedness and response efforts.

After significant discussion of the issues including, but not limited to, the roles of local, state, and federal governments in emergency preparedness and response, the recent roles of, and challenges faced by, the boards of pharmacy as a result of 2005 Hurricanes Katrina and Rita, and needed partnerships between the boards of pharmacy and the public and private sectors in coordinating emergency preparedness and response efforts, the Task Force conveyed a number of recommendations to the NABP Executive Committee. Additionally, as charged, the Task Force members produced this comprehensive model template, the "Emergency and Disaster Preparedness and Response Planning: A Guide for the Boards of Pharmacy."

The Guide contains, among other items, NABP's "Recommendations for Preparing and Responding to an Emergency or Disaster," a "Model Emergency and Disaster Preparedness Response Plan," and "Model Rules for Public Health Emergencies," as well as emergency and disaster resources provided to boards by NABP.

NABP's "Recommendations for Preparing and Responding to Emergency or Disaster" provide a timeline for the boards of pharmacy to employ in preparing and responding to an event. Its "Early Preparation for an Emergency or Disaster" section directs the boards of pharmacy to work proactively to create emergency and disaster preparedness and response plans, work with the state legislature to enact emergency dispensing and other related provisions, develop rules, and develop a contact list of public and private stakeholders, with whom the board of pharmacy may work in the case of a disaster. The "Immediate Response to an Emergency or Disaster" section provides a foundation for the board's response in the event of an impending situation, outlining when the board should activate its emergency or disaster plans, make initial contact with various stakeholders crucial to response efforts, and release important information to licensees, the general public, the media, and others. The "Short-Term Response" section addresses the board's response up to 72 hours post-event, directing the board to continue its immediate response

activities, while basing further action upon up-to-date information received from, for example, state and federal agencies, or others. Finally, the "Long-Term Response" section addresses the continuing response activities, including, if necessary, efforts to restore board operations, sustain communications with important stakeholders, and provide continuous updates to licensees, the general public, the media, or others.

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The "Model Rules for Public Health Emergencies," which are intended to be incorporated into the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act),* and which are outlined above, provide suggested statutory and/or regulatory language intended to enable pharmacists, pharmacies, and other licensees to assist in the management and containment of a public health emergency or similar crises. The provisions address emergency prescription drug orders, emergency refill dispensing, temporary recognition of non-resident licensure, and temporary or mobile pharmacy facilities.

Finally, the Guide outlines emergency and disaster resources provided by NABP to assist boards in their efforts. Currently, NABP offers expedited licensure transfer and verification services to allow boards to swiftly register and recognize non-resident pharmacists and pharmacy technicians.

Introduction

Emergency and Disaster Preparedness and Response: Roles of Federal, State, and Local Governments

To effectively prepare for and respond to an emergency or disaster, boards of pharmacy must have an understanding of the interplay between federal, state, and local governments in preparedness and response management. By understanding these processes at the various levels of government, boards of pharmacy are better enabled to develop robust emergency and disaster plans that are complementary to existing broader based efforts aimed at minimizing the impact of a disaster. This summary is not intended to provide a complete and comprehensive review of the intricate governmental layers of preparedness and response, thus boards of pharmacy are encouraged to contact their state emergency management agencies as well as consult the references included in this guidance (see Reference section).

Federal Preparedness and Response[1]

National Incident Management System, National Response Plan, and the US Department of Homeland Security

The National Incident Management System (NIMS) provides a nationwide template enabling federal, state, local, and tribal governments and private sector and nongovernmental organizations to work together to effectively and efficiently prevent, prepare, respond to, and recover from domestic incidents of all causes, sizes, or complexities. The National Response Plan (NRP), utilizing NIMS, serves as the principal guide for managing domestic crises. The product of Homeland Security Presidential Directive (HSPD)-5, NRP provides a comprehensive approach to preventing, preparing for, responding to, and recovering from events with potential national or long-term implications, such as terrorist attacks, natural disasters, and public health emergencies requiring a coordinated federal response. Designed to allow maximum flexibility, the Plan can be partially or fully implemented, as appropriate, to meet the unique operational and information-sharing requirements of any emergency situation. The Plan outlines how the federal government will coordinate with various state, local, tribal, private-sector, and other nongovernmental entities. Together, the NRP and NIMS integrate a number of entities, public and private, federal and local, for an overall national framework for emergency preparedness and response.

Established pursuant to the Homeland Security Act of 2002, the US Department of Homeland Security's (DHS) purpose is to prevent terrorist attacks within the United States and reduce the vulnerability to, minimize damage from, and assist in recovery efforts as a result of domestic terrorism, natural disasters, and other emergencies. DHS is the lead federal department in crises and emergency management. The Federal Emergency Management Agency (FEMA), under the auspices of the DHS, is charged with preparing for all domestic hazards and managing the federal response and recovery efforts following any national incident. FEMA also initiates

proactive mitigation activities, trains first responders, and manages the National Flood Insurance Program.

Emergency Support Function Annexes

Emergency Support Function Annexes (ESFAs) are the primary means by which the federal government provides assistance to state, local, and tribal governments, or to federal departments and agencies conducting missions of primary federal responsibility, during actual or potential domestic incidents. Outlined in the NRP, ESFAs include specific emergency support resources (eg, transportation, firefighting, public health services) available for dispatch during incidents requiring a coordinated federal response. Currently, the NRP contains 15 ESFAs coordinated by a multitude of various federal agencies such as the US Department of Transportation, the Environmental Protection Agency, and Coast Guard.

US Department of Health and Human Services

Specifically, ESFA # 8, primarily coordinated by the US Department of Health and Human Services (HHS), entails public health and medical services contingencies. When required, HHS would be responsible for providing supplemental assistance to state, local, and tribal governments by assessing the medical and behavioral health needs of victims as well as providing public health surveillance and the medical personnel, equipment, and supplies. HHS would provide these services utilizing its umbrella agencies, offices, and divisions, such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the US Public Health Service (PHS).

For example, PHS, a division of HHS, is the federal nonmilitary, uniformed force of health care professionals who work in various agencies, including FDA, Indian Health Service (IHS), Federal Bureau of Prisons, Immigration and Customs Enforcement (ICE), Coast Guard, and CDC.[2] The mission of PHS is to provide highly trained and mobile health professionals who carry out programs to promote the health of the nation, understand and prevent disease and injury, ensure safe and effective drugs and medical devices, deliver health services to federal beneficiaries, and furnish health expertise in time of war or other national or international emergencies. The PHS is led by the Surgeon General and consists of approximately 6,000 officers in the following professional categories: nursing, dentistry, pharmacy, dietetics, medical, veterinary, engineering, environmental health (including physical, occupational, speech, and audiology therapy), and other health services (including social work, optometry, statistics, and computer science).

Strategic National Stockpile[3]

The Strategic National Stockpile (SNS), operated by CDC, is a national repository of antibiotics, chemical antidotes, antitoxins, life-support medications, IV administration devices, airway maintenance supplies, and medical/surgical items. The SNS is designed to supplement and re-supply state and local public health agencies in the event of a national emergency anywhere and at any time within the US or its territories. During a national emergency, state, local, and private stocks of medical supplies will be depleted quickly. While the SNS is not a first response tool, state and local first responders and health officials can use the SNS to bolster their responses to a national emergency.

The SNS is organized for flexible response. The first line of support is the immediate-response 12-hour Push Packages. These are caches of pharmaceuticals, antidotes, and medical supplies for rapid delivery in the early hours of an event. These Push Packages are positioned in strategically located, secure warehouses and are ready for immediate deployment to a designated site within 12 hours of the federal decision to deploy SNS assets.

If an incident requires additional pharmaceuticals and/or medical supplies, follow-up vendor-managed inventory (VMI) supplies are shipped to arrive within 24 to 36 hours. If the agent is well defined, VMI can be tailored to provide pharmaceuticals, supplies, and/or products specific to the suspected or confirmed agent(s). In this case, the VMI could serve as the first option for immediate response from the SNS Program.

State/Local Preparedness and Response[1]

At the local level, first responders such as law enforcement, fire personnel, and emergency medical teams are often the first to arrive at an incident site. In some instances, a federal agency in the local area may act as a first responder and may advise or assist state or local officials in accordance with agency authorities and procedures. Mutual aid agreements provide mechanisms to mobilize and employ resources from neighboring jurisdictions to support the incident command. When state resources and capabilities are overwhelmed, governors may request federal assistance under a presidential disaster or emergency declaration.

As outlined in the NRP, the governor is responsible for the safety and welfare of the people of that state or territory. The governor has the following responsibilities: (1) coordinates state resources to prevent, prepare for, respond to, and recover from incidents in situations such as terrorism, natural disasters, accidents, and other contingencies; (2) under certain emergency conditions, typically has police powers to make, amend, and rescind orders and regulations; (3) provides leadership in communicating to the public and in helping people, businesses, and organizations cope with the consequences of any declared emergency within state jurisdiction; (4) encourages participation in mutual aid and implements authorities for the state to enter into mutual aid agreements, with other states, tribes, and territories to facilitate resource-sharing; (5) serves as commander-in-chief of state military forces; and (6) requests federal assistance when state or tribal capabilities are insufficient or have been exhausted.

A mayor or city or county manager, as a jurisdiction's chief executive, is responsible for the public safety and welfare of the people of that jurisdiction. Similar to the governor, the mayor or city or county manager has the following responsibilities: (1) coordinates local resources to prevent, prepare for, respond to, and recover from incidents involving all hazards including terrorism, natural disasters and accidents, and other contingencies; (2) depending on state or local law, has extraordinary powers to suspend local laws and ordinances, such as to establish a curfew, direct evacuations, and, in coordination with the local health authority, to order a quarantine; (3) provides leadership in communicating to the public and in helping people, businesses, and organizations cope with the consequences of any domestic incident within the jurisdiction; (4) negotiates and enters into mutual aid agreements with other jurisdictions to

facilitate resource-sharing; and (5) requests state and, if necessary, federal assistance through the governor of the state when the jurisdiction's capabilities have been exceeded or exhausted.

Recommendations for Preparing and Responding to an Emergency or Disaster[4]

Modeled and adapted from the Georgia Pharmacy Foundation's *An Action Plan for State Pharmacy Associations to Respond to Natural or Man-Made Disasters (March 1996)*, the "Recommendations for Preparing and Responding to Emergency or Disaster" section provides a timeline for the boards of pharmacy to employ in preparing and responding to an event

I. Early Preparation for an Emergency or Disaster

In most cases, emergencies and disasters occur with little or no warning. In order to be best prepared, boards of pharmacy can start developing contingency plans well in advance. Specifically, boards of pharmacy should consider the following:

1. Creating an emergency and disaster preparedness and response plan specifically for the board of pharmacy;
2. Working with the state legislature to enact emergency dispensing and other related provisions;
3. Developing and maintaining a contact list of local/state government agencies and national pharmacy organizations;
4. Developing and maintaining a contact list of local/regional pharmaceutical manufacturers, wholesale drug distributors, and pharmacies that could donate and provide storage sites and transportation resources for critical drugs and supplies; and
5. Educate licensees on board efforts related to emergency or disaster planning.

1. Create an Emergency and Disaster Preparedness and Response Plan

Using the NABP Model Emergency and Disaster Preparedness and Response Plan as a guide, boards of pharmacy can take perhaps the most important step in preparing for an emergency or disaster, ensuring that the board has an operational plan to remain functional to continue to fulfill its mission of protecting the public health. See **Appendix A**: "NABP Model Emergency and Disaster Preparedness and Response Plan."

2. Work with the State Legislature to Enact Emergency Dispensing and Other Related Provisions

If the state pharmacy practice act currently contains emergency dispensing provisions, the boards should review the provisions and revise if necessary. For guidance, boards of pharmacy should consider utilizing NABP's "Model Rules for Public Health Emergencies," found in **Appendix B**. In addition, boards should work with the legislature and appropriate agencies to ensure the state's "emergency declaration" contains language appropriate to trigger the activation of emergency rules related to needed pharmacy services. Boards should also work within their states to ensure that pharmacists are designated as "first responders" in a disaster or emergency so they have access to needed prophylactic medications and vaccines.

3. **Develop and Maintain a Contact List of Local/State Government Agencies and National Pharmacy Organizations**

Boards of Pharmacy should have contact information for local offices and agencies, including, but not limited to, the governor's office, the department of public health, state emergency management agency, county health departments, and the state/local chapter of the American Red Cross, as well as national pharmacy organizations. Boards of pharmacy should also consider meeting with the local agencies to ensure that emergency or disaster plans of these agencies complement the board's emergency or disaster plan. Boards should also be familiar with local law enforcement security plans in the event of an emergency or disaster.

4. **Develop and Maintain a Contact list of Local/Regional Pharmaceutical Manufacturers, Wholesale Drug Distributors, Pharmacies, Pharmacists and Technicians**

Local and regional pharmaceutical manufacturers, wholesale drug distributors, and pharmacies are in a unique position to help in an emergency or disaster by lending temporary storage and shipping facilities as well as providing critical drugs and supplies. Developing contacts, and in some cases memorandums of understanding, with these entities in advance of an emergency or disaster could dramatically improve the response time in getting supplies where they are needed in addition to maintaining the integrity of drugs and supplies. In some cases, transportation may also be challenged. Boards should also consider working with these entities to assist in transportation efforts.

Boards may also consider developing a list of pharmacists and technicians who are willing to volunteer their services in the case of an emergency or disaster. In the alternative, a board may choose to simply access such a list if one is maintained by a national group. Such a list may contain volunteer credentials, such as CPR, first aid, or immunization certification.

5. **Educate Licensees on Board Efforts Related to Emergency or Disaster Planning**

Boards should keep licensees up-to-date on emergency and disaster planning efforts via Web sites, newsletters, etc. Boards may also consider developing or distributing a template for state-licensed pharmacies to use in developing a disaster or emergency plan.

II. Immediate Response to an Emergency or Disaster

At the point an emergency or disaster is declared, there may be limited time to respond. Boards of pharmacy should take the following steps prior to an emergency or disaster:

1. Activate the Board emergency or disaster response plan, place board of pharmacy members and staff on "standby;"

2. Initiate contact with local/state emergency management agencies, pharmaceutical manufacturers, wholesale drug distributors, pharmacies, and other entities if necessary;
3. Initiate contact with NABP regarding the potential need for emergency or disaster resource assistance; and
4. Alert licensees, national and local pharmacy associations, and the public.

1. Activate Emergency or Disaster Response Plan, Place Board of Pharmacy Members and Staff on "Standby"

In the event of an emergency or disaster, the board of pharmacy executive director/secretary or chief administrator, as the primary crisis manager, should activate the board's emergency or disaster plan. During normal business hours, the primary crisis manager may consider conducting a brief meeting to provide information to staff regarding the status of the disaster, including such information as anticipated staffing needs or mandatory evacuation of the board facility. If not during normal business hours, depending on the specific emergency or disaster, the primary crisis manager may call the emergency planning team (as described in Appendix A) to assist in contacting staff at home with specific updates and instruction.

Boards of pharmacy should also consider alternative forms of communication with board members, staff, and the public in case normal modes of communication are compromised.

2. Initiate Contact with Local/State Emergency Management Agencies, Pharmaceutical Manufacturers, Wholesale Distributors, Pharmacies, and Other Entities

As an emergency or disaster unfolds, the board of pharmacy will most likely not be working unilaterally but, instead, will be working in concert with other entities, particularly local/state government agencies. Boards of pharmacy should initiate contact with the appropriate entities to begin to coordinate efforts and optimize response. Working with local/state government agencies and, in some cases, with federal agencies, boards can serve as an important link to private entities, such as pharmaceutical manufacturers, wholesale drug distributors, and others in the pharmaceutical industry that may be of assistance. Boards should also contact other entities, such as Internet and telecommunication service providers, to discuss the maintenance of communication lines during and in the immediate aftermath of the emergency or disaster.

3. Initiate Contact with NABP Regarding the Potential Need for Emergency or Disaster Resource Assistance.

Boards of pharmacy should contact NABP regarding the potential need for emergency or disaster resource assistance. NABP provides expedited licensure verification and transfer services to ensure adequate personnel are available to provide needed pharmacy care services in affected areas. Other services provided by NABP are described in **Appendix C**.

4. Alert Licensees, National and Local Pharmacy Associations, and the Public

Boards should make particular efforts to alert all necessary parties of the impending emergency or disaster. The board of pharmacy should consider using its Website as a tool in communicating crucial information, not only to the public and licensees, but also to board members and staff, if necessary. Boards may consider posting on their Web sites emergency-related regulations, such as emergency dispensing provisions, or emergency-related notices, such as board office relocation and temporary contact information. Also, boards may consider using calling trees, blast faxes, and email list servs to disseminate information.

III. Short-Term Response: The First 72 Hours Post-Disaster

The period immediately following an emergency or disaster is perhaps the most critical in that there may be limited or no state or federal aid available (typical time frame for a state or federal disaster to be declared is 72 hours) and local resources may be quickly overwhelmed. Communication systems may be challenged and public utilities, like electricity and water, may be unavailable. Also, information concerning an accurate assessment of the emergency or disaster may be limited. During this critical time, boards of pharmacy should:

1. Continue to employ the board's emergency or disaster response plan;
2. Initiate contacts with local/state government agencies to determine the public's medical and health needs;
3. Maintain communication with wholesale distributors and pharmaceutical manufacturers to ensure that adequate supplies of drugs and supplies are available and accessible;
4. Maintain use of NABP emergency and disaster resource assistance; and
5. Provide frequent information and updates, if possible, through various channels to licensees, the public, and other identified entities.

1. Continue to Employ the Board's Emergency or Disaster Response Plan

During this phase of the disaster, the board of pharmacy should be assessing internal needs in order to maintain identified critical operations. This may include increasing staffing and equipment or determining whether or not the board will be operating at an alternate location. Depending on the emergency or disaster, the board may decide to cease all operations.

2. Initiate Contacts with Local/State Government Agencies to Determine Public Health Needs

The board of pharmacy serves as an important resource to local/state emergency management agencies as the needs of the public are assessed. The board of pharmacy is equipped to serve as one of the primary coordinating agencies for the receipt and distribution of supplies through its contacts with the private industry. Additionally, through its relationship with local and state professional associations, the board of pharmacy may also be able to help with the coordination and disbursement of volunteers.

3. **Maintain Communication with Pharmaceutical Manufacturers, Wholesale Drug Distributors, and Pharmacies to Ensure Adequate Supplies of Drugs and Medical Equipment are Available and Accessible**
Depending on information available to the board of pharmacy regarding initial assessments of the emergency or disaster, the board may be able to relay specific drug and supply needs to the industry, including but not limited to, identifying temporary or mobile facilities.

4. **Maintain Use of NABP Emergency and Disaster Resource Assistance**
Continued use of NABP's expedited licensure verification and transfer services will ensure that adequate numbers of pharmacists and pharmacy technicians can be put into place to serve needed areas.

5. **Provide Frequent Information and Updates through Various Channels to Licensees, the Public, and Other Identified Entities**
The board serves as an important source of information and should utilize appropriate means of communication to provide updates and other specifics. For example, the board may want to post its temporary license applications on its Web site or provide consumers with important information on obtaining necessary medications.

IV. Long-Term Response: 72 hours to 30 Days (Possibly Longer) Post Disaster

The long-term recovery period following an emergency or disaster varies and, depending on the disaster, may be as short as 30 days or as long as 12 months. Although the board's focus will shift from acute to more long-term concerns, the board should continue the efforts that began immediately following the disaster. These efforts include working to restore and maintain critical board operations, sustaining communications with important stakeholders, such as local/state emergency response agencies and pharmaceutical industry contacts; and providing updates to the public and licensees. The board may also need to assist licensees in their efforts to restore operations by providing guidance on associated regulatory aspects pertaining to the emergency or disaster.

Appendix A:
Model Emergency and Disaster Preparedness and Response Plan[5]

The NABP Model Emergency and Disaster Preparedness and Response Plan is intended to assist boards of pharmacy in developing a tailored and detailed emergency preparedness and response document. Modeled and adapted from the *Ready Business Mentoring Guide: Working with Small Businesses to Prepare for Emergencies*, issued by the US Department of Homeland Security, this Plan consists of six comprehensive sections and provides a template to develop or supplement existing emergency and disaster plans.

With local/state government agencies serving as primary emergency responders, boards of pharmacy are strongly encouraged to proactively work with their local/state agency counterparts to learn about existing emergency preparedness and response plans and local/state specific contingencies into their own plans. In addition, by collaborating with local/state emergency response agencies, these entities can become aware of the resources and capabilities of the board in an emergency or disaster situation.

I. Emergency Planning

A. Emergency Planning Team

A successful emergency or disaster preparedness and response plan is dependent upon the board's continued commitment to encourage and authorize an emergency planning team to create a plan. First the board should determine which staff will be responsible for the development of the plan. The identified staff should be knowledgeable about most facets of the organization's operations and facilities. The board may consider involving other employees from every level of the board so the plan can appropriately take into account all divisions of the board.

Emergency Planning Team

The following board and staff members will participate in emergency planning and crisis management: (include name, title, contact information)

1. _____
2. _____
3. _____
4. _____
5. _____

B. Emergency Contact Information

The board should also have the emergency contact information, including cell phone numbers, for all staff and board members, and insurance company contact information (if applicable and whether or not it is state or privately issued insurance).

Emergency Contact Information

Staff

Name	Cell No.	Work No.	Home No.	e-mail

Board Members

Name	Cell No.	Work No.	Home No.	e-mail

Insurance Provider _____

Street Address _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____ E-Mail _____

Contact Name _____ Policy Number _____

C. Risk Assessment

In developing a robust emergency or disaster preparedness and response plan, the board and its emergency planning team should evaluate the probability or risk that specific disasters or emergencies may impact the board. Threats could include both natural and man-made, ranging from floods and power outages to technological threats and terrorism. By knowing what types of risks your board is more likely to encounter, the emergency planning team will be better equipped to determine the needs of the board in the event of a disaster or emergency as well as focus efforts on preparation activities on situations that are likely to affect the board.

The board may consider completing the following Risk Assessment Survey. Rank the likelihood that any of the following scenarios will occur, the impact it will have on the board, and the amount of warning time available before it occurs.

Risk Assessment Survey

Disaster/Emergency	Likelihood of Occurrence (1 to 5)	Impact on Board (minimal, moderate, severe)	Warning Time (Days, Hours, Min)
Natural			
Flood			
Hurricane			
Thunderstorm/ Lightning			
Tornado			
Winter Storm/Extreme Cold			
Extreme Heat			
Earthquake			
Volcano			
Landslide			
Tsunami			
Fire			
Wildfire			
Pandemic Illness			
Technological			
Hazardous Material			
Nuclear Power Plant			
Power Outage			
Cyber Security			
Nuclear Blast			
Radiological Dispersion Device			
Disasters/ Emergencies Specific to the Board			

1.			
2.			
3.			

D. Emergency Supplies

The emergency planning team should prepare a list of supplies that the board should store on location. Items to include may be essentials such as water and food, and a basic first-aid kit. See below for a list of recommended emergency supplies. The emergency planning team should also determine an appropriate place to store these items so as to minimize any potential damage in the event of a disaster, while at the same time ensuring easy accessibility. The emergency planning team may also consider obtaining signage that would allow the office to communicate to emergency personnel in case of quarantine. The board may also encourage employees to maintain their own personal emergency supply kits, including items such as medications, a mini-flashlight, an emergency whistle, water, snacks, etc.

Essential documents, including this Emergency and Disaster Preparedness and Response Plan, building plans, insurance documents, contracts, employee contact information, and electronic back up media should be sealed in a waterproof/fireproof container, with a duplicate set of items stored offsite.

The following are recommended emergency supplies. The board should include additional items as it deems appropriate. Additionally, each staff member should be encouraged to prepare a personal emergency supply kit, consisting of a three-day supply of necessities, including medications.

Emergency Supplies – Minimum Three-Day Supply

	Water (one gallon of water per person per day for drinking and sanitation)
	Food (non-perishable)
	Battery-operated radio and extra batteries
	NOAA weather radio and extra batteries
	Flashlights and extra batteries
	First-aid kit
	Whistle (to signal for help)
	Dust or filter masks (minimum N-95 mask)
	Moist towelettes (for sanitation)
	Tool Kit, including wrench or pliers to turn off utilities
	Can opener for food
	Plastic sheeting and duct tape to "seal the room"
	Garbage bags and plastic ties for personal sanitation
	Satellite phone/two-way radios
	Safety glasses
	Sleeping bags/pillows
	Gore-Tex or waterproof rain suit
	Rubber boots

	Other:
	Other:
	Other:

E. Immunizations

The following is a list of immunizations recommended for all board of pharmacy members and staff to ensure appropriate preparation for an emergency or disaster:

Immunization	Frequency
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	

F. Staff Education and Training

The board should conduct regularly scheduled staff education and training seminars to provide information, identify needs, and develop preparedness skills, including, on a regular basis, emergency preparedness and safety information in board communications, e-mails, and staff meetings to complement formalized training efforts. The identification and consideration of staff with disabilities or special communication needs is key. The board may consider drills where staff actually performs their designated emergency or disaster functions. The board may consider maintaining staff education and training records.

The board may also direct staff to walk the evacuation route to a designated area where procedures for accounting for all personnel are tested. Processes and procedures should be re-evaluated and revised based on information gathered from practice drills. If boards share office space with another entity, coordinating emergency plans should be considered.

II. Maintaining Board of Pharmacy Operations

A. Primary/Secondary Crisis Managers

It is important for boards to designate a primary and a secondary crisis manager. In most cases, the board's executive director or secretary serves as the primary crisis manager and the assistant executive director or chief compliance officer/investigator serves as the secondary crisis manager. The role of the primary crisis manager is to oversee and execute the emergency or disaster response plan and serve as the primary spokesperson for the board. In the event that the primary crisis manager is unavailable, the secondary crisis manager will assume that role.

Primary Crisis Manager

Name/Title _____

Phone _____

Alternative Phone _____

E-Mail _____

Secondary Crisis Manager
Name/Title _____

Phone _____

Alternative Phone _____

E-Mail _____

B. Remote Electronic Access to Data

Should the board office become inaccessible, it will be important for board staff and board members to have remote electronic access to certain data and operating systems. List each staff and board member, the data and operating systems to which they will have access, and the mechanism by which they will have access.

Staff name _____
Data and operating systems to be accessed _____
_____
_____
_____
Mechanism to access _____
_____
_____

Staff name _____
Data and operating systems to be accessed _____
_____
_____
_____
Mechanism to access _____
_____
_____

Staff name _____
Data and operating systems to be accessed _____
_____
_____
_____
Mechanism to access _____

Board member name_____
Data and operating systems to be accessed _____

Mechanism to access _____

Board member name_____
Data and operating systems to be accessed _____

Mechanism to access _____

Board member name_____
Data and operating systems to be accessed _____

Mechanism to access _____

C. Alternate Location Site

The board may want to designate an alternate location from which to continue board operations if the board office becomes inaccessible. For example, the board may operate from a residential location or perhaps a location provided by the state.

Alternate Location Site

Address_____

City, State_____

Phone _____

D. Critical Functions

Before an emergency or disaster occurs, the board should determine the most critical and vital functions needed to maintain board operations. In determining these functions, boards may consider identifying the various resources and procedures that are absolutely essential to each function. Boards should also assess how its functions, both internally and externally, affects demands for staff, materials, procedures and equipment. For completion of this section, list the board's critical functions, the staff charged with maintaining each function in the event of an emergency or disaster, and the procedures for maintaining each function and recovering from the emergency or disaster. It is also important to distinguish which functions are critical depending on the nature of the emergency or disaster.

Our Critical Functions

The following is a prioritized list of critical functions, staff, and procedures needed to maintain and recover from a disaster.

Function #1 _____
Staff in Charge _____
Action Plan _____
_____
_____
_____
_____
_____

Function #2 _____
Staff in Charge _____
Action Plan _____
_____
_____
_____
_____
_____

Function #3 _____
Staff in Charge _____
Action Plan _____
_____
_____
_____
_____
_____

Function #4 _____
Staff in Charge _____
Action Plan _____
_____
_____

Function #5 _____
Staff in Charge _____
Action Plan _____

Function #6 _____
Staff in Charge _____
Action Plan _____

E. Suppliers and Contractors

Another element in emergency preparedness involves identifying the supplier, contractors, resources and other entities with which the board interacts on a daily basis. In many cases, developing relationships with more than one company can help maintain critical board operations in case the board's primary contractor cannot service the board's needs.

Necessary Materials/Services _____

Primary Supplier

Company Name_____

Street Address_____

City_____ State _____ Zip Code_____

Phone _____Fax_____ E-Mail _____

Contact Name_____ Account Number _____

Secondary Supplier
Company Name_____

Street Address_____

City_____ State_____ Zip Code_____

Phone _____Fax_____ E-Mail:_____

Contact Name_____ Account Number:_____

Materials/Services Provided _____

Necessary Materials/Services _____
_____
_____
_____
_____

Primary Supplier
Company Name_____

Street Address_____

City_____ State_____ Zip Code_____

Phone _____Fax_____ E-Mail:_____

Contact Name_____ Account Number:_____

Secondary Supplier
Company Name_____

Street Address_____

City_____ State_____ Zip Code_____

Phone _____Fax_____ E-Mail:_____

Contact Name_____ Account Number:_____

F. Record Preservation

The preservation of vital records is crucial for timely and prompt restoration of board operations in the event of an emergency or disaster. Identifying the minimum information needed to perform critical board operations should guide the board on the specific records

and the equipment that will be needed to access and use the information found in such records.

The board should copy (electronic and/or hard document) all critical records and data on a regular basis and keep copies offsite. There are off-site data storage businesses that can assist the board in copying and storing all critical records and data. In addition, backing up all computer systems on a regular basis and labeling vital records for easy identification and access can be particularly helpful.

If a disaster is imminent, the board may consider using heavy-duty plastic bags to store, protect, and transport smaller electronic equipment and paper files. The board should also identify critical equipment and documents that should be removed or relocated to another designated location.

Record Preservation

Vital board records and data that must be copied and stored off site are:

1. This Emergency and Disaster Preparedness and Response Plan
2. Site maps
3. Insurance policies
4. Accounting records, including payroll data
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

The **on-site** location(s) of the records listed above are as follows:

1. This Plan – _____
2. Site maps – _____
3. Insurance policies – _____
4. Accounting records – _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

The **off-site** location(s) of the records listed above are as follows:

1. This Plan – _____
2. Site maps – _____
3. Insurance policies – _____
4. Accounting records – _____
5. _____
6. _____
7. _____

8. _____
9. _____
10. _____

The person responsible for copying board records and ensuring the appropriate on- and off-site storage is _____(Staff Person/Title).

III. Communication

A. Crisis Communication Plan

The board's ability to effectively communicate with staff, licensees, local authorities, and the public during an emergency or disaster is critical. As the board develops a crisis communication plan, it should contemplate how it would communicate with both internal (ie, staff) and external (ie, licensees) entities considering normal modes of communication may be inoperable (ie, lack of electricity, telephone lines down, etc). In developing a crisis communication plan, the board should contemplate all possibilities, from short-term disruption to full communications failure. The board should also inquire with its various communication vendors about emergency preparedness and response capabilities.

The board may consider developing a telephone call tree, password-protected pages on the board's Web site, an e-mail listserv alert, or a call-in voice recording to communicate with staff, members and licensees during an emergency or disaster. Maintaining an updated staff, member, and licensee roster with multiple contact phone numbers, fax numbers, and e-mail addresses is recommended.

Boards should also consider maintaining a Web page with current licensee information to assist in necessary license verification efforts in the case of an emergency or disaster.

The board may also consider contacting the media with updates or using prerecorded public service announcements to communicate with the public. Maintaining an up-to-date media contact list containing phone and fax numbers and e-mail addresses is recommended.

Crisis Communication Plan

During an emergency or disaster, the board will communicate with STAFF by:

_____
_____
_____
_____

During an emergency or disaster, the board will communicate with BOARD MEMBERS by:

_____
_____

During an emergency or disaster, the board will communicate with LICENSEES (including pharmacists, pharmacies, students, technicians, etc.) by:

During an emergency or disaster, the board will communicate with other STATE AGENCIES by:

During an emergency or disaster, the board will communicate with the PUBLIC by:

IV. Evacuation Planning

A. Evacuation Plan

One of the most critical decisions during an emergency or disaster can be choosing whether to remain on site or to evacuate the premises. It is strongly recommended that boards follow the warnings and direction from local, state, and federal officials. To facilitate this effort, an Evacuation Plan should be developed by the board.

Overall, the Plan should, at a minimum, describe a mechanism for identifying all persons present in the board office, describe the disaster warning system, identify the evacuation route, designate an assembly site, and identify staff responsible for ensuring all persons present in the board office are accounted for and for shutting down critical operations and securing the office or building.

As mentioned above, the Plan should include a mechanism for identifying all persons present in the board office, including staff and visitors, so that all can be accounted for in case of an evacuation. An office visitor sign-in sheet and employee punch clock records can be used for this purpose. Boards should also consider the fact there may be staff or visitors with disabilities who may require assistance in evacuating the building.

The description of the warning system should include the audio and/or visual signals to be used to warn of a disaster or emergency, building site maps with critical utility locations and clearly-marked emergency routes, with entry and exit points on the maps and throughout the building. Evacuation routes should be clearly posted and the board

may consider installing emergency lighting or the use of flash lights in case there is loss of electricity.

In identifying an assembly site, boards should choose at least two locations; a primary and a secondary location in the case evacuees must move farther away from the board office.

The Plan should identify an assembly site manager who will be responsible for the assembly site during a disaster or emergency, and who will account for staff and visitors to determine any missing persons. The Plan should also identify a staff person responsible for shutting down critical operations and securing the board office or building. In addition, the Plan should identify the person who will determine when it is safe to halt the Evacuation Plan and issue an "all clear."

When the Evacuation Plan is finalized, staff should be trained and boards should consider practicing the evacuation procedures. If the board office is located in a high rise building or shares building space with other entities, the board should attempt to coordinate and practice with those entities to avoid confusion and gridlock. Boards should encourage staff to inform fellow staff if they cannot get to or must depart from the assembly site.

Evacuation Plan

Description of Disaster Warning System:

_____

_____

_____

_____

Disaster Warning System will be tested (frequency):

_____

_____

Assembly Site Manager and Alternate:

_____

_____

Primary assembly site:

_____

_____

Secondary assembly site:

_____

_____

Staff responsible for shutting down critical operations and securing board office:

_____

_____

Staff responsible for issuing "All Clear":

_____

_____

V. Shelter-in-Place Planning

A. Shelter-in-Place Plan

There may be situations when it is best for persons present in the board office to take shelter immediately; for instance, during a tornado, chemical incident, or other incident where concerns are for the survival of board staff and visitors. If the board is advised by local authorities to take shelter, all persons should do so immediately. In reality, staff can not be forced to take shelter, but staff should be informed in advance of policies and procedures on sheltering to maximize cooperation in the event it is necessary. To facilitate this effort, a Shelter-in-Place Plan should be developed by the board.

Overall, the Plan should, at a minimum, describe a mechanism for identifying all persons present in the board office, describe the disaster warning system, identify the shelter, and identify staff responsible for ensuring all persons present in the board office are accounted for and for shutting down critical operations and securing the office or building.

As mentioned above, the Plan should include a mechanism for identifying all persons present in the board office, including staff and visitors, so that all can be accounted for. An office visitor sign-in sheet and employee punch clock records can be used for this purpose. Boards should also consider the fact that there may be staff or visitors with disabilities who may require assistance in taking shelter.

As with the Evacuation Plan, the Shelter-in-Place Plan should include a description of the warning system, including the audio and/or visual signals to be used to warn of a disaster or emergency, building site maps with critical utility locations and clearly-marked emergency routes, with entry and exit points on the maps and throughout the building. The route to the shelter should be clearly posted and the board may consider installing emergency lighting or the use of flash lights in case there is loss of electricity.

Identifying the shelter location, will depend on the specific circumstances. For example, in the case of a tornado, storm cellars or basements provide the best protection. If underground shelter is not available, an interior room or hallway on the lowest floor is best. Staff should be instructed to stay away from windows, doors, exterior walls, and corners. Staff should be advised to gather in the center of the room. In the event of air contamination as a result of an agent released from a chemical plant or a bioterrorism attack, the board may be instructed by local authorities to take shelter and "seal the room" in an inside room on a higher floor. By sealing the room, a temporary protective measure is created forming a barrier between the inside of the board office and the air contaminated outside. To "seal the room" effectively, the board should:

1. Close the board office and direct everyone inside, preferably to an interior room with the fewest windows;
2. Lock all doors, close all windows, air vents, and fire place dampers;
3. Turn off all fans, air conditioning, and forced air heating systems;
4. Locate emergency supplies (unless contaminated);
5. Seal all windows, doors and air vents with plastic sheeting and duct tape. The board may consider measuring, cutting and labeling the sheeting in advance to save time;
6. Stay tuned via radio, television, and/or Internet for official news and instructions as they become available.

The Plan should identify a shelter manager who will be responsible for the shelter during a disaster or emergency, and who will account for staff and visitors to determine any missing persons. The Plan should also identify a staff person responsible for shutting down critical operations and securing the board office or building. In addition, the Plan should identify the person who will determine when it is safe to halt the Shelter-in-Place Plan and issue an "all clear."

When the Shelter-in-Place Plan is finalized, as with the Evacuation Plan, staff should be trained and boards should consider practicing sheltering procedures. If the board office is located in a high rise building or shares building space with other entities, the board should attempt to coordinate and practice with those entities to avoid confusion and gridlock. Boards should encourage staff to inform fellow staff if they cannot get to or must depart from the shelter.

Shelter-in-Place Plan

Description of Disaster Warning System:

_____
_____
_____
_____

Disaster Warning System will be tested (frequency):

_____
_____

Shelter Manager and Alternate:

_____
_____

Storm Shelter Location:

_____
_____

"Seal the Room" Shelter Location:

_____
_____

Staff responsible for shutting down critical operations and securing board office:

_____

_____

Staff responsible for issuing "All Clear":

_____

_____

VI. Protecting Resources

A. Cyber Security and Computer Inventory

For most organizations, computers are crucial to most operations. It is vital, therefore, that organizations address cyber security. Every computer is vulnerable to cyber-security threats necessitating that all organizations dependent on computers for crucial functions take the appropriate measures to guard against hacking and viruses.

Boards should consider such precautions as:

- Regularly using up-to-date anti-virus software
- Discouraging staff from opening e-mails from unknown or unwanted sources
- Using hard-to-guess passwords
- Installing firewalls
- Electronically backing up data and storing it off-site
- Regularly downloading security update patches
- Assessing computer operation security on a regular basis
- Training personnel on policies and procedures in the event the board's computer system becomes infected

In the event that computer hardware is damaged or lost, boards should maintain an accurate inventory of all computers and hardware, including the serial and model numbers, date purchased, and cost. Boards should also include the company that provides repair and support for computer hardware.

Cyber Security

The board will do the following to protect computer hardware:

_____

_____

_____

_____

_____

The board will do the following to protect computer software:

_____

_____

In the event the board's computers are destroyed, the board will:

B. Supporting Board Staff Health and Well Being

Encouraging staff to prepare for emergencies may help individuals and their families minimize the impact of the emergency or disaster on their lives. Staff will be able to re-establish routines faster and the board, as a whole, will be able to recover more quickly. Boards should keep in mind that staff may have special recovery needs and boards should be prepared to support employee health after a disaster.

In assisting the staff, the board should:

1. Encourage adequate food, rest, and recreation;
2. Provide for time at home to tend to family needs;
3. Encourage an open door policy that facilitates care when needed;
4. Create an atmosphere where staff can talk openly about their fears and hopes; sharing with others can speed personal recovery;
5. Reassure families will be supported; worries about family well-being can consume staff that has experienced a disaster;
6. Re-establish routines, when possible; workplace routines facilitate recovery by providing an opportunity to be active and to restore social contact;
7. Offer professional counselors to help staff address their fears and anxieties;
8. Once the need to listen for emergency instructions has passed, limit television, radio and other external stresses.

C. Securing the Board Facilities

The board can also take preparatory steps to protect and secure its facilities in the event of an emergency or disaster. For example:

1. Install fire extinguishers and smoke detectors in appropriate places and ensure that staff members are instructed on appropriate use;

2. Plan to provide building and site maps with critical utility locations and clearly-marked emergency routes to fire fighters or other first responders in the event of a disaster;
3. Consider whether or not the board could benefit from automatic fire sprinklers, alarm systems, closed circuit TV, access control, security guards or other security systems;
4. Secure ingress and egress. Consider all the ways in which people, products, supplies, and other things get into and leave your building or facility;
5. Plan for mail safety. The nation's battle against terrorism takes place on many fronts, including the mailrooms of U.S. companies. A properly informed and well-trained workforce can overcome such threats;
    a. Teach employees to be able to quickly identify suspect packages and letters. Warning signs include:
        i. Misspelled words
        ii. No return address
        iii. Excessive use of tape
        iv. Strange discoloration or odor
    b. The United States Postal Service (*www.usps.com*) suggests that if a suspect letter or package is identified:
        i. Do not open, smell, touch or taste
        ii. Immediately isolate suspect packages and letters
        iii. Move out of the area and do not let others in
        iv. Quickly wash with soap and water and remove contaminated clothing
        v. Contact local law enforcement authorities
6. Post emergency numbers for easy reference;
7. Identify and comply with all local, state, and federal codes and other safety regulations that apply to your business; and
8. Talk to your insurance provider about what impact any of these steps may have on your coverage.

D. Assessing Facility Air Protection

In some emergencies, microscopic particles may be released into the air. A building can provide a barrier between contaminated air outside and people inside, but there are ways to improve building air protection. Depending on the size of the building and the design and layout of the heating, ventilating, and air conditioning (HVAC) system, there may be simple steps building owners and managers can take to help protect people from some airborne threats.

Boards should:

1. Know the HVAC system. Building owners, managers and employers should take a close look at the site's system and be sure it is working properly and is well-maintained, and ensure that any security measures do not adversely impact air quality or fire safety;
2. Develop and practice shut-down procedures for the HVAC system;
3. Secure outdoor air intakes. HVAC systems can be an entry point and means of distributing biological, chemical and radiological threats:

a. Limit access to air intake locations to protect the people inside a building from airborne threats. Air intakes at or below ground level are most vulnerable because anyone can gain easy access;
b. Consider relocating or extending an exposed air intake, but do not permanently seal it;

4. Determine if you can feasibly upgrade the building's filtration system:
   a. Increasing filter efficiency is one of the few things that can be done in advance to consistently protect people inside a building from biological and some other airborne threats;
   b. Carefully consider the highest filtration efficiency that will work with a building's HVAC system;
5. Use HEPA (High Efficiency Particulate Arrester) filter fans. These individual units have highly efficient filters that can capture very tiny particles, including many biological agents. While these filters are excellent at filtering dander, dust, molds, smoke, many biological agents, and other contaminants, they will not stop chemical contaminants.

Appendix B:
Model Rules for Public Health Emergencies

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article II

...

Section 201. Designation

The responsibility for enforcement of the provisions of this Act is hereby vested in the Board of Pharmacy. The Board shall have all of the duties, powers, and authority specifically granted by or necessary for the enforcement of this Act, as well as such other duties, powers, and authority as it may be granted from time to time by applicable law. In the event of a declared State of Emergency, the Board may waive the requirements of this Act in order to protect the public health, safety, or welfare of its citizens and to facilitate the provision of Drugs, Devices, and Pharmacist Care services to the public.

...

Article III

...

Comments

Section 201. Comment

In states where centralized prescription filling or centralized prescription processing are not permitted, states may consider allowing the performance of such activities in a declared State of Emergency.

...

Section 303. Comment

See NABP's Model Rules for Public Health Emergencies for language that addresses the temporary recognition of non-resident pharmacist licensure in the case of a declared State of Emergency issued due to a Public Health Emergency.

Model Rules for the Practice of Pharmacy

...

Section 2. Personnel.

A. Duties and Responsibilities of the Pharmacist-in-Charge

...

(2) The Pharmacist-in-Charge has the following responsibilities:

...

(vii) a procedure for the operation of the Pharmacy, to the extent that the Pharmacy can be safely and effectively operated and the Drugs contained therein can be safely stored and Dispensed, in the event of a fire, flood, pandemic or other natural or man-made disaster or emergency; and

(vii) policies and procedures for reporting to the Board the occurrence of any fire, flood, or other natural or man-made disaster or emergency within 10 days of such occurrence.

...

Section 2A(2)(n) Comment

States should recognize that hospitals, in order to prepare for a disaster or emergency, may be stocking emergency supplies of medications in areas outside the licensed Pharmacy. Hospitals should be encouraged to expand the space allotted to the licensed Pharmacy area to accommodate the need to store emergency supplies.

Model Rules for Public Health Emergencies

Section 1. Purpose and Scope

By the provision of these rules by the Board, the primary purpose of the section is to enable Pharmacists and Pharmacies to assist in the management and containment of a Public Health Emergency or similar crisis within the confines of a regulatory framework that serves to protect the welfare and health of the public.

Section 2. Definitions.

(a) "Declared Disaster Areas" are areas designated by the state or federal authorities as those that have been adversely affected by a natural or man-made disaster and require extraordinary measures to provide adequate, safe and effective health care for the affected population.

(b) "Emergency Prescription Drug Order" means a standing Prescription Drug Order issued by the State Health Officer for Pharmacists to Dispense designated Prescription Drugs during a Public Health Emergency requiring mass Dispensing to expeditiously treat or provide prophylaxis to large numbers of Patients.

(c) "Mobile Pharmacy" means a Pharmacy that is self propelled or movable by another vehicle that is self propelled.

(d) "Public Health Emergency" means an imminent threat or occurrence of an illness or health condition caused by terrorism, bioterrorism, epidemic or pandemic disease, novel and highly fatal infectious agent or biological toxin, or natural or man-made disaster, that poses a substantial risk of a significant number of human

fatalities or incidents of permanent or long-term disability that is beyond the capacity of local government or nongovernmental organizations to resolve.

(e) "State of Emergency" means a governmental declaration, usually issued as a result of a Public Health Emergency, that may suspend certain normal functions of government, alert citizens to alter their normal behaviors, and/or direct government agencies to implement emergency preparedness plans.

(f) "Temporary Pharmacy Facility" means a facility established as a result of a Public Health Emergency or State of Emergency to temporarily provide Pharmacy services within or adjacent to Declared Disaster Areas.

Section 3. Emergency Prescription Drug Order

(A) For the duration of a State of Emergency issued due to a Public Health Emergency, a Pharmacist may Dispense a Prescription Drug pursuant to an Emergency Prescription Drug Order if the Pharmacist:

(1) performs, to the extent possible, a Prospective Drug Regimen Review and Patient Counseling in accordance with these rules;

(2) reduces the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Prescription Drug Order," and files and maintains the record as required by state and federal law.

Section 4. Public Health Emergency Refill Dispensing

(A) For the duration of the State of Emergency issued due to a Public Health Emergency in the affected state and in other states engaged in disaster assistance pursuant to a governmental declaration or rule of the Board, a Pharmacist may Dispense a refill of a Prescription Drug, not to exceed a thirty (30) day supply, without Practitioner authorization if:

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates it is an "Emergency Refill Prescription," and maintains the record as required by state and federal law, as well as state and federal disaster agencies for consideration for possible reimbursement programs implemented to ensure continued provision of care during a disaster or emergency; and

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Presciber's authorization and that authorization of the Practitioner is required for future refills.

(B) For the duration of the State of Emergency, in an effort to provide patients with the best possible care in light of limited Drug availability and/or limited information on patients' current Drug therapy, a Pharmacist may initiate or

modify Drug therapy and Dispense an amount of such Drug to accommodate a patient's health care needs until that patient may be seen by a Practitioner. Pharmacists performing such activities must utilize currently accepted standards of care when initiating or modifying Drug therapy. These activities may be undertaken if:

(1) in the Pharmacist's professional judgment, the Prescription Drug is essential to the maintenance of the Patient's life or to the continuation of therapy;

(2) the Pharmacist makes a good faith effort to reduce the information to a form that may be maintained for the time required by law or rule, indicates that Drug therapy has been initiated or modified due to a disaster or emergency, and maintains the record as required by state and federal law; and

(3) the Pharmacist informs the Patient or the Patient's agent at the time of Dispensing that the Prescription Drug is being provided without the Practitioner's authorization and that authorization of the Practitioner is required for future refills.

(C) The Practitioner and Pharmacist shall not incur any liability as a result of the performance of these activities in good faith pursuant to this section.

Section 5. Temporary Recognition of Non-Resident Licensure

(A) When a State of Emergency is declared due to a Public Health Emergency:

(1) a Pharmacist not licensed in this State, but currently licensed in another state, may Dispense Prescription Drugs in areas affected by the Declared Disaster during the time that the State of Emergency exists if:

(a) the Board can verify current licensure in good standing of the Pharmacist directly with the state or indirectly via a third-party verification system; and

(b) the Pharmacist is engaged in a legitimate relief effort.

(2) a Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern not registered or licensed in this State, but currently registered or licensed in another state, may assist the Pharmacist in Dispensing Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(a) the Board can verify current registration or licensure in good standing of the Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern directly with the state or indirectly via a third-party verification system; and

(b) the Certified Pharmacy Technician, Pharmacy Technician, or Pharmacy Intern is engaged in a legitimate relief effort.

(3) a Wholesale Drug Distributor not licensed in this State, but currently licensed in another state, may Distribute Prescription Drugs in affected Disaster Areas during the time that the State of Emergency exists if:

(a) the Board can verify current licensure in good standing of the Wholesale Drug Distributor directly with the state or indirectly via a third-party verification system; and

(b) the Wholesale Drug Distributor is engaged in a legitimate relief effort.

(4) the temporary recognition of non-resident licensure or registration shall cease with the termination of the State of Emergency.

Section 6. Temporary Pharmacy Facilities or Mobile Pharmacies

(A) Pharmacies located in Declared Disaster Areas, non-resident Pharmacies, and Pharmacies licensed in another state but not licensed in this State, if necessary to provide Pharmacy services during a State of Emergency, may arrange to temporarily locate or relocate to a Temporary Pharmacy Facility or Mobile Pharmacy if the Temporary Pharmacy Facility or Mobile Pharmacy:

(1) is under the control and management of the Pharmacist-in Charge or designated supervising Pharmacist;

(2) is located within the Declared Disaster Area or affected areas;

(3) notifies the Board of its location;

(4) is properly secured to prevent theft and diversion of Drugs;

(5) maintains records in accordance with laws and regulations of the state in which the disaster occurred; and

(6) ceases the provision of services with the termination of the State of Emergency, unless it is successfully licensed by the Board of Pharmacy in accordance with Article V of this Act.

(B) The Board, in accordance with Board rules, shall have the authority to approve or disapprove Temporary Pharmacy Facilities or Mobile Pharmacies and shall make arrangements for appropriate monitoring and inspection of the Temporary Pharmacy Facilities and Mobile Pharmacies on a case-by-case basis. Approval of Temporary Pharmacy Facilities and Mobile Pharmacies will be based on the need, type, and scope of Public Health Emergency, as well as the ability of the Temporary Pharmacy Facilities or Mobile Pharmacies to comply with state and federal drug law.

(C) A Temporary Pharmacy Facility wishing to permanently operate at its temporary site must be licensed by the Board in accordance with Article V of this Act.

(D) Mobile Pharmacies placed in operation during a State of Emergency may not operate permanently, unless approved by the Board.

Comments

...

Section 1. Comment

States may consider adding the following, more detailed language, which specifically addresses drug disposal and reporting requirements in the case of an emergency or disaster, to their emergency rules or guidelines:

Disposal of Prescription Drugs in Pharmacies Affected by a Certain Disasters

1. For pharmacies that sustain flood and/or fire damage in the Prescription department or other damage resulting in an irrevocable loss of the Drug inventory, the entire Drug inventory, including Drugs awaiting pick up by Patients, becomes unfit for Dispensing.

In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy.

2. For Pharmacies that experience a loss of power for an extended period of time, the Drug inventory must be evaluated for continued product integrity using USP standards. For example, medications with labeling requiring storage at "controlled room temperature" must be kept at between 68? F and 77? F, with brief deviations of between 56? F and 86?F.. Medication inventories found to have been stored outside of USP standards become unfit for Dispensing. In such a case, an accurate record of Prescription Drug losses should be prepared by the Pharmacy. For Pharmacies with questions on USP product integrity standards, contact USP at 800/227-8772.

Reporting of Theft or Loss of Controlled Substances During an Emergency or Disaster

1. In circumstances of theft by looting, burglary, etc., where evidence or witnesses indicate the medications were taken by someone, the nearest DEA Diversion Field Office must be notified by telephone, facsimile, or brief written message of the circumstances of the theft immediately upon discovery. In addition, the Pharmacy must complete *DEA Form 106– Report of Theft or Loss of Controlled Substances*, found at www.deadiversion.usdoj.gov, to formally document the actual circumstances of the theft and the quantity of controlled substances involved, once this information has been conclusively determined.
2. In circumstances of damage or where Drugs were irrevocably lost to flooding or other circumstance, such information must be reported on *DEA Form 41 – Registrants Inventory of Drugs Surrendered*, found at www.deadiversion.usdoj.gov.
3. The amount stolen or lost may need to be calculated by taking the most recent controlled substances inventory, adding the amount purchased since that date, then subtracting the amount Dispensed and Distributed since that date. In the absence of a calculated amount, a best estimate should be reported.

Disposal of Prescription Drugs Irrevocably Lost in an Emergency or Disaster

1. Controlled Substances.
   Reverse Distributors, either individually or in concert with other contractors, are equipped to dispose of controlled substances. Contact your primary Distributor for their recommendations for a reverse Distributor or contact a reverse Distributor directly.
2. Contaminated Medical Debris
   Non-controlled substance Prescription Drugs and Devices contaminated with flood water or other contaminants should be disposed of using a medical waste transportation, processing, and disposal system vendor. Such vendors must be licensed by the state.
3. Hazardous Debris
   Materials are deemed hazardous if they are ignitable, corrosive, toxic, or reactive. Prescription Drugs considered hazardous include, but are not limited to, epinephrine, nicotine, nitroglycerin, physostigmine, reserpine, selenium sulfide, chloral hydrate, and many chemotherapy agents, such as cyclophosphamide, chlorambucil, and daunomycin. Other hazardous items that might be found in a Pharmacy include paints, varnishes and thinners, alcohol, batteries, mercury thermometers, and blood pressure cuffs. It is recommended that Pharmacies handle all contaminated Prescription medications as hazardous debris and dispose of it using a hazardous waste collection and disposal company. These companies must be licensed by the state.

4. Commercial Waste
Over-the-counter Drugs and other store shelf material may be disposed of in the commercial waste stream.

Section 2(B). Comment
Boards may consider identifying the official who has authority to issue an "Emergency Prescription Drug Order" and reviewing this on a regular basis.

Section 3(A)(1). Comment
Although these services are important, in times of a disaster or emergency, it may not be possible to perform a Prospective Drug Review or provide counseling on Dispensed Drugs.

Section 4(A). Comment
Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure these provisions are applicable to controlled substances.

Section 4(B)(2). Comment
Boards should be cognizant that state and federal disaster agencies, to ensure continued provision of care during disasters or emergencies, have programs that consider reimbursement requests for medication providers and may request Board assistance in the dispersal of funds. Records of dispensing will likely be needed for possible reimbursement consideration. In addition, records may also be used for post-event evaluation of care.

Section 5(A)(1)(a). Comment

If the information cannot be verified directly by the Board of Pharmacy in which the Non-Resident Pharmacist is licensed, NABP's Clearinghouse may be utilized to verify that a Non-Resident Pharmacist has not had disciplinary action taken against his or her license.

Section 6(A). Comment
Boards may consider contacting the US Drug Enforcement Administration ahead of time to ensure that controlled substances may be delivered to and Dispensed from temporary or mobile Pharmacy facilities.

Section 6(a)(3). Comment
Boards may choose to require "approval" of a Temporary Pharmacy Facility or a Mobile Pharmacy, as opposed to requiring only "notification." "Notification" may imply that the Board of Pharmacy has approved the location of the Temporary Pharmacy Facility or Mobile Pharmacy.

Section 6(d). Comment
Although many states do not allow the permanent or temporary licensure of Mobile Pharmacies, states that do allow the licensure of Mobile Pharmacies may consider implementing special requirements for permanent licensure; for example, a state may limit Mobile Pharmacies to operation only by nonprofit organizations and only in communities that are medically underserved.

Appendix C:
Emergency and Disaster Resources Provided by NABP

NABP Clearinghouse/Expedited Licensure Transfer Services

The NABP Clearinghouse serves as a national database of educational, competence, licensure, and disciplinary information on pharmacists licensed by the boards of pharmacy. On a daily basis, the Clearinghouse provides boards with the information necessary to determine the acceptability and qualifications of candidates requesting the transfer of examination scores and licenses into their jurisdictions. In an emergency or disaster scenario, the Clearinghouse can be used to quickly verify licensure in good standing for boards that must quickly issue temporary licenses to licensure transfer applicants. In addition, these verification requests can be expedited, with information provided to boards verbally, via e-mail, in written format or in any form requested by the board. Pharmacists and other licensees who are deemed clear of disciplinary sanctions and/or whose licenses have been verified, can also be listed on the NABP Web site.

References

1. US Department of Homeland Security. National Response Plan. December 2004. Available at *www.dhs.gov/interweb/assetlibrary/NRP_FullText.pdf* Accessed October 2, 2006.
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5. US Department of Homeland Security. *Ready Business Mentoring Guide: Working with Small Business to Prepare for Emergencies*. Available at *www.ready.gov/business/_downloads/mentor_guide.pdf* Accessed October 2, 2006.

County of San Diego Request for Medications for Emergency Responders

County of San Diego

Community Epidemiology
Emergency & Disaster Medical Services
HIV/STD Hepatitis
Immunization
Maternal, Child and Family Health Services
Public Health Laboratory
PH Nursing/Border Health
TB Control & Refugee Health
Vital Records

JEAN M. SHEPARD
DIRECTOR

WILMA J. WOOTEN, M.D., M.P.H.
INTERIM PUBLIC HEALTH OFFICER

HEALTH AND HUMAN SERVICES AGENCY

PUBLIC HEALTH SERVICES
1700 PACIFIC HIGHWAY, SAN DIEGO, CALIFORNIA 92101-2417
(619) 531-5800 FAX (619) 515-6707

EMERGENCY MEDICAL SERVICES
6255 Mission Gorge Road
San Diego, CA 92120-3599
(619) 285-6429 Fax: (619) 285-6531

TO: California State Board of Pharmacy
c/o Virginia Herold, Virginia.herold@dca.ca.gov

CC: Kenneth H Schell, PharmD (ken.h.schell@kp.org)
Subject: Home Med Kits

SITUATION

The State of California has a Memorandum of Agreement (MOA) with the Center for Disease Control and Prevention (CDC) for receipt, distribution, and dispensing of the Strategic National Stockpile (SNS), massive reserves of medications and medical supplies strategically placed throughout the nation to supplement local and county governments when their resources are exhausted. However, any state, region, or local jurisdiction must face the possibility that federal and state resources may not be available immediately to assist, if multiple areas require assets simultaneously. Therefore, local and county governments should prepare accordingly.

When an act of bioterrorism or other public health emergency occurs, it may be necessary to initiate mass dispensing of medications countywide under the direction of the County Public Health Officer (PHO). Specifically, weaponized anthrax can cause catastrophic loss of life within 48-72 hours and is considered a nationwide vulnerability risk by the CDC. Initial responders such as public health, first responders, and identified other critical public service employees, will initiate response plans and operations that include dispensing antibiotics to the public within 48 hours to save as many lives as possible. In order for this to occur, these first wave or initial responders will have priority in receiving medication so that they are prepared to meet the public's needs.

TARGET

In order to meet the above need, the County of San Diego has decided to purchases and "forward place" as many as 500,000 regimen bottles (7-14 day regimen of either doxycycline or ciprofloxacin) specifically for first responders (ie. fire, police, hazmat, etc). The desire is to place the majority of these bottles in their homes to cover them and their family, and the remainder placed in secure & temperature controlled areas of the employment site for on duty personnel. Of note, the

CDC recently completed a similar initiative, a test pilot in St Louis*. We have been in contact with the lead coordinator (Dr. Linda Neff) and more information will be forthcoming soon from that pilot.

Because of the volume of bottles to be forward placed and the logistics of doing so, meeting the prescription requirement for each individual patient and labeling each bottle with the individual patient name will be extremely difficult if not impossible. Rather we'd like to be able to dispense regimen bottles with a standard pre-formatted label that omits the actual patient and physician name. That information would be stored and readily accessible in a central database. See attached picture below for what the label will resemble.

QUESTION

We're seeking the advice of the California State Board of Pharmacy on how best to achieve the target goal.

1) Would we obviate the Rx & labeling requirement if the County of San Diego retained ownership, without "transfer of custody" to the employee/patient, in that the inventory would remain property of San Diego County, such that, forward placed inventory would ONLY be activated in the case of a declared emergency event that under which time the Rx requirements would be obviated?
2) Could we apply for a waiver from the board, waiving the prescription and labeling requirements?
3) Other ideas/options?

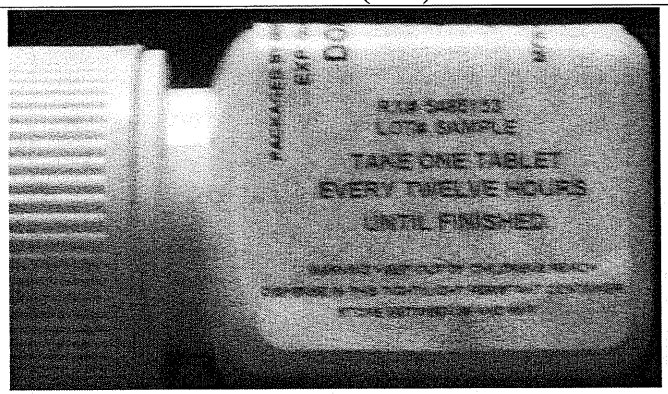
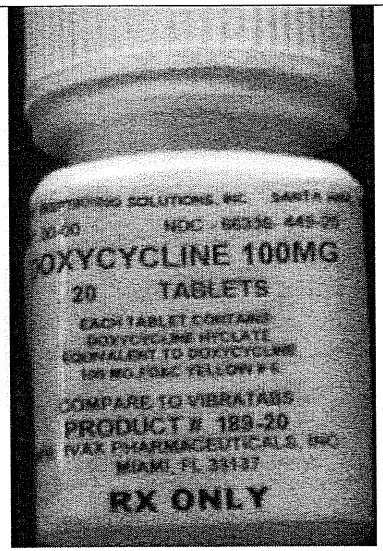
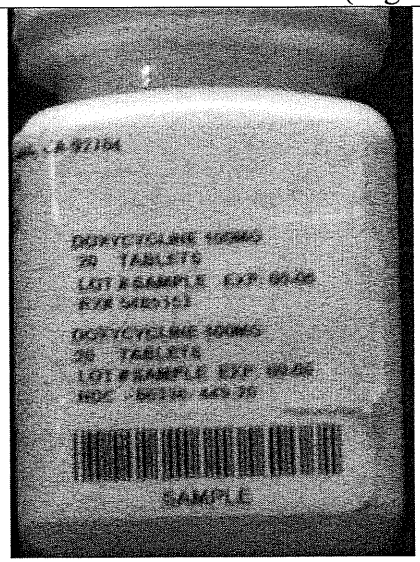
Thank you for your attention to this matter.

Sincerely,

Shirley A. Jett, M.S.N., RN, PHN
Strategic National Stockpile Coordinator
Cities Readiness Initiative Coordinator

* http://www.gsnmagazine.com/mar_06/cdc_antibiotics.html

ATTACHMENT

Side View (Left)	Front View	Side View (Right)
		
Directions	Drug, lot, ndc, repackaging info, etc	tear off receipts get put into a log against the employee & family names.

ATTACHMENT

Sample Label (Doxy)

PACKAGED BY DISPENSING SOLUTIONS, INC.
SANTA ANA, CA 92704
MANUFACTURED BY WEST-WARD PHARMACEUTICAL CORP.
EATONTOWN, NJ 07724

NDC 66336-449-20

FPO

STORE AT 20°-25°C (68°-77°F)
[SEE USP CONTROLLED ROOM TEMPERATURE].

DO NOT USE UNLESS DIRECTED
BY THE HEALTH OFFICER

DOXYCYCLINE 100 mg

EACH TABLET CONTAINS:
DOXYCYCLINE HYCLATE USP
EQUIVALENT TO DOXYCYCLINE
100 mg, FD&C YELLOW #6.

20 TABLETS

USUAL DOSAGE: Take one tablet every 12 hours.

RX ONLY

LOT# xxxxxx EXP: xxx-xx
RX# 1000000001 (999-9999)

DOXYCYCLINE 100 mg
20 TABLETS
LOT# xxxxxx EXP: xxx-xx
RX# 1000000001
NDC 66336–449-20

DOXYCYCLINE 100 mg
20 TABLETS
LOT# xxxxxx EXP: xxx-xx
RX# 1000000001
NDC 66336–449-20

KEEP OUT OF THE REACH OF CHILDREN
DISPENSE IN THIS TIGHT/LIGHT
RESISTANT CONTAINER

Sample Label (Cipro)

PACKAGED BY DISPENSING SOLUTIONS, INC.
SANTA ANA, CA 92704
MANUFACTURED BY HIKMA PHARMACEUTICALS
AMMAN, 11118 JORDAN

NDC 66336-903-20

FPO

STORE AT 20°-25°C (68°-77°F)
[SEE USP CONTROLLED ROOM TEMPERATURE].

DO NOT USE UNLESS DIRECTED
BY THE HEALTH OFFICER

CIPROFLOXACIN 500 mg

EACH TABLET CONTAINS:
CIPROFLOXACIN HCl USP
EQUIVALENT TO 500 mg
CIPROFLOXACIN.

20 TABLETS

USUAL DOSAGE: Take one tablet every 12 hours.

RX ONLY

LOT# xxxxxx EXP: xxx-xx
RX# 1000000001 (999-9999)

CIPROFLOXACIN 500 mg
20 TABLETS
LOT# xxxxxx EXP: xxx-xx
RX# 1000000001
NDC 66336–903–20

CIPROFLOXACIN 500 mg
20 TABLETS
LOT# xxxxxx EXP: xxx-xx
RX# 1000000001
NDC 66336–903–20

KEEP OUT OF THE REACH OF CHILDREN
DISPENSE IN THIS TIGHT/LIGHT
RESISTANT CONTAINER

Agenda Item 5

Mobile Community Clinic Licensure

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: May 23, 2007**

From: **Board of Pharmacy**

Subject: **Mobile Community Clinics**

The board has received a request from the Community Clinic Association of Los Angeles County to consider a request that mobile clinics be licensed with the board without having a permanent "brick and mortar" address.

Currently the board requires the brick and mortar address be licensed as a clinic, not the vehicle (or trailer) itself. The association wants the board's licensure program for clinics for mobile clinics to be more like the policies of the Department of Health Services, which seems to license the vehicle, not the brick and mortar address.

A copy of this request is attached. The association's director, Paul Drogichen, will attend our meeting to provide information directly to the committee.

Clinics

Mobile Community Clinic Licensing

Mobile clinics present a challenge in their medication dispensing operations.

The challenge to the entity is to dispense in a proper and lawful manner while remaining economically viable.

The challenge to the Board of Pharmacy is to understand how they operate and to create workable regulations for the clinics to operate under. In the absence of these regulations then the board should understand that unless they vigorously disseminate information on what they believe to be improper dispensing and unless they police the clinics with vigor, mobile clinics will dispense legend medications where they are the appropriate therapy. Why do I believe this? Because both Board of Pharmacy licensed and unlicensed mobile clinics are dispensing today. Many if not most of the unlicensed ones do not realize that in fact a license from the Board of Pharmacy is required to dispense. There are others which are fully licensed but when we have analyzed their operation we have found various degrees of understanding of what is required for proper dispensing (but we find this in the brick and mortar setting also).

Some mobile clinics actually carry and dispense a larger array of medications than some fixed site clinics.

Current Situation

There are Community Clinic Mobiles that have been licensed by both DHS and the Board of Pharmacy.

- Most of these clinics have a "brick and mortar" administrative office where medications are stored, etc. (see below) but with no fixed clinic site.

- Inspectors have visited these clinics and validated their operations (although the inspections have been of an inconsistent nature).

There are DHS licensed Mobile Community Clinics which have only administrative fixed sites (no fixed clinic site) who have been recently told that they cannot have a Board of Pharmacy Clinic Dispensary License.

There are "brick and mortar" community clinics that have been told by inspectors that their Mobile does not need to be licensed since physicians may dispense from their "brown" bags.

- This is not true as the physicians do not own the medications and usually mid-levels (who are licensed to dispense in clinics) staff the mobiles.

There are Community clinics that do not have a "brick and mortar" licensed clinic but do have one or more mobiles individually licensed by the Department of Health Services.

To review, Community clinic mobile clinics are licensed and inspected by the California State Dept of Health Services (or their contract agency in some counties). The regulations which they function under speak to medication and the required oversight by a pharmacist. They do not mention the requirement of a BOP clinic license. Most mobile clinics are "stand alone" operations. They do not have a "brick and mortar" licensed clinic base. They do have a brick and mortar administrative support office base which usually houses a storage space for keeping the overstock supply of medications and also in many cases this is where they store medications between runs if they cannot maintain temperature control on the vehicle when it is parked. Many operations have a single vehicle (which can be motorized or in some cases it is a towed trailer). However a considerable number operate multiple units (which are individually licensed by DHS) out of the same base address.

In fact, it is the multiple unit operations which have created the licensing questions. In the past when a mobile applied for licensing and gave you a base address along with the other required DHS licensing and paperwork, a BOP clinic permit was issued. It was then further validated by Board of Pharmacy inspector visits (with positive inspection reports). When we inquired about how to properly differentiate multiple mobiles based at the same address (we suggested adding the VIN to the physical address) we were told that you do not license mobiles for dispensing—they must have a brick and mortar licensed clinic base as the point of licensing for the clinic permit. This appears to be inconsistent with previously licensed mobiles where the DHS Clinic license resides with the mobile.

Recommendations for mobile licensing:
(this section may need additional input)

Board of Pharmacy licensing and identification should be uniform with State DHS procedures.

Mobile Community Clinics would follow the same licensing requirements and application procedures as a fixed site clinic with regard to the need for a state DHS site permit (that is, full time clinics would be required to have their own DHS site permit while a part time (less than 20 hour clinic) could operate as a satellite of another site owned by the corporation but in this case the parent site would be brick and mortar (if the Board of Pharmacy preferred, all mobiles regardless of hours of operation could be required to have their own DHS permit).

- Each mobile unit should be identified by using the Vehicle Identification Number (VIN) in combination with the "base" address which houses the administrative offices and drug supply storage (if any).

- The administrative office could be at a site where a clinic has a fixed brick and mortar clinic with each having a separate clinic dispensary license. The mobile would be clearly identified as being a mobile clinic and as above it would be identified by its base address and VIN.

- Mobiles would be required to post their site schedule at their administrative site. They would also post the schedule on their website if they maintain one.

- Dispensary records such as medication purchases, dispensing logs, pharmacist of record reports, and other patient records could be either kept on the mobile or at the administrative site. Where they are being kept is to be clearly delineated on the clinic's policy and procedure manual. Like other BOP licensed operations, these clinics can also request off site storage waivers when needed.

- Control of dispensary cabinets, etc. on the mobile and supply rooms or cabinets at the administrative site used for medication storage will be the responsibility of licensed medical personnel. Only licensed medical personnel will maintain control of keys to these medication storage areas.

Agenda Item 6

State Protocol for Immunizations

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: May 17, 2007**

From: **Board of Pharmacy**

Subject: **Immunizations**

At the last Licensing Committee Meeting, Dr. Jeff Goad, a professor from USC made a presentation to the committee about establishing state protocols for immunizations by pharmacists. Dr. Goad stated that pharmacists can administer immunizations in 44 states. California is one of these states. At the April 2007 board meeting the board voted to develop a statutory modification to allow pharmacists to administer immunizations pursuant to a state adopted protocol.

Business and Professions Code section 4052(a)(9) allows a pharmacist to administer immunizations pursuant to a protocol with a prescriber. According to testimony provided by Dr. Goad, physicians are reluctant to accept the liability for this action, even though it has wide support.

Additionally, Health and Safety Code section 1261.3 allows for a pharmacist to administer both the influenza and pneumococcal immunizations for a certain patient population in a skilled nursing facility pursuant to standing orders.

Provided with this memo are:

- A draft of proposed language. This language may need to be refined after the committee discusses criteria.
- Information and draft protocols previously provided by Dr. Goad.

Staff is recommending that the language should reference the recommendations of the Advisory Committee on Immunization Practices (ACIP) rather than placing each protocol in pharmacy regulation.

The committee will need to discuss the draft language as well as determine the appropriate parameters under which this provision should occur. We also need to encourage our stakeholders to provide comments. Some factors to consider include:

- Age of patient
- Types of Immunizations
- If additional training/CE should be required
- Recordkeeping
- Other exclusions

4052. (a) Notwithstanding any other provision of law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
(2) Transmit a valid prescription to another pharmacist.
(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.
(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.
(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized
by Section 4052.2.
(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.
(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.
(8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.
(9) Administer immunizations pursuant to a protocol with a prescriber or pursuant to the recommendations of the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention.
(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.
(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.
(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

Pharmacy Immunization Protocol

Pharmacy Name

Authorizing Prescriber Statement for Vaccination

<Pharmacist, RPh> of the *<Pharmacy>*, and other licensed pharmacists employed by the *<Pharmacy>*, pharmacy students of the *<Pharmacy>*, acting as delegates for *<Physician>*, M.D. according to and in compliance with Article 3 of the Business and Professional Code 4052.(a).(4).(C) and B&P code 4052.(a).(5).(A).(iii) of the California Pharmacy Scope of Practice section, will independently determine the need for and administer vaccinations and epinephrine, on the premises of the USC Campus Pharmacies, or a suitable alternate location as authorized under Appendix A, and for a fee.

Qualifications of Persons Administering Vaccine

1. CPR certified (BLS) – American Red Cross or American Heart Association or equivalent
2. Certificate of completion of an appropriate immunization program (see Appendix B)

Vaccine(s) to be administered (see Appendix C)

- Influenza (IM and Intranasal)
- Tetanus-diphtheria (Td)
- Tetanus-diphtheria-pertussis (Tdap)
- Pneumococcal (PPV23 adult)
- MMR (for adults)
- HPV
- Meningococcal (MCV4 and MPSV4)
- Varicella Zoster
- Herpes Zoster
- Hepatitis B

Policies

1. A standard form will be used to document immunizations and the pharmacy will maintain a patient record of administration, including, but not limited to, patient name, date, vaccine given (manufacturer, lot #, and expiration date), and signature of person administering vaccine (Appendix D)
2. The screening form contained in this protocol will be maintained as documentation (Appendix D)
3. The current Vaccine Information Statement for each vaccine will be discussed and given to each patient
4. Written informed consent will be obtained for each patient prior to vaccination (Appendix D)
5. The pharmacist will notify the patient's primary care provider of immunization when contact information is available (see Appendix E).
6. All supplies needed for vaccination and vaccine adverse event management as detailed in this protocol will be available and not expired.
7. Authorizing prescriber will be periodically notified of vaccinated patients

Emergencies

Authorize use of the Pharmacy Procedure and Standing Orders for Management of Allergic or Anaphylactic Reactions for emergencies (Appendix F)

Physician Authorization:

Physician Name: *Physician, M.D.* Affiliation (Clinic): _____

Phone: _____ Fax: _____ Pager/Mobile: _____

Physician CA license number: _____ Physician DEA number: _____

_____ _____

Date *<Physician>*, MD

Principle Authorized Pharmacist

_____ _____

Date *<Pharmacist, RPh>*

This authorization will be in effect for 2 years unless rescinded earlier in writing by either party. Any changes in the protocol must be agreed upon by both parties.

APPENDIX A. Alternate Location Request for Vaccine Administration

The pharmacists and intern pharmacists authorized under this protocol may provide vaccination services at the following location in California for the time period specified. All provisions under the policy, procedure and protocol shall remain in effect. Cold chain for storage and subsequent administration of vaccines shall be maintained.

Location and/or Name of Event:_____

Address:_____

Date(s):_____

Signature:

_____ **Date** _____

<Physician> , M.D.

APPENDIX B. Immunization Training

Certificate of completion of an appropriate immunization-training program that includes the *current guidelines and recommendations of the Advisory Committee on Immunization Practices* and uses the core curriculum of the CDC (Epidemiology and Prevention of Vaccine-Preventable Diseases). An appropriate training program shall include, at a minimum, instruction on how to:

A. Identify persons eligible for vaccination based on current ACIP guidelines. (Factors taken into consideration will include age, vaccination status (e.g., persons previously unvaccinated or due for vaccination according to the recommended schedule), or the presence of a medical condition that puts them at high risk, etc.).

B. Screen patients for contraindications and precautions to vaccination (e.g.. severe illness, previous allergic reaction, egg allergy, etc.).

C. Provide adequate information to patients or their guardians regarding the risks for and benefits of a vaccine and documenting the delivery of that information. (i.e. Distribution/discussion of Vaccination Information Statements as required by law).

D. Administer vaccines.

E. Monitor patients for adverse events.

F. Manage anaphylactic reactions according to protocol

G. Report adverse outcomes to the Vaccine Adverse Events Reporting System (VAERS).

H. Record administration of a vaccine(s)

I. Provide documentation of vaccine administration to patients and whenever possible, their primary-care providers.

J. Follow Universal Precautions and Infection Control and pertinent OSHA regulations (i.e. for Blood Bourne Pathogens).

Appendix C. Criteria for Patients to Receive Vaccine

Standing Orders for Administering Hepatitis B Vaccine to Adults

Purpose: To reduce morbidity and mortality from hepatitis B virus (HBV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses may vaccinate patients who meet the criteria below.

Procedure:

1. Identify adults in need of hepatitis B vaccination based on the following criteria:
   a. Persons less than 19 years of age who have not received the vaccine
   b. Age 19 years or older meeting any of the following criteria:
      - having had more than one sex partner in the previous 6 months, a recently acquired sexually transmitted disease, or recent treatment for a sexually transmitted disease
      - male who has had sex with males
      - injection drug user
      - sex partner or household member of a person who is chronically infected with HBV (including an HBsAg-positive adopted child)
      - at occupational risk of infection through exposure to blood or blood-contaminated body fluid (e.g., health care worker, public safety worker, trainee in a health professional or allied health school)
      - client or staff of an institution for the developmentally disabled
      - hemodialysis patient or patient with early renal failure (who will become a dialysis patient)
      - receiving clotting-factor concentrate
      - planning to travel to or live in a high endemic area of the world for more than 6 months and will have close contact with the local population; also short-term travelers who are likely to have contact with blood (e.g., in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease
      - housed in a long-term correctional facility
2. Screen all patients for contraindications and precautions to hepatitis B vaccine:
   a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
   b. **Precautions:** a moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis
4. For persons 20 years of age or older, administer 1.0 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle. For persons 19 years of age or younger, administer 0.5 mL hepatitis B vaccine IM (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of hepatitis B vaccine to complete each patient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 8 weeks between the second and third doses, and at least 4 months between the first and third doses.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to hepatitis B vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

Immunization Action Coalition • 1573 Selby Avenue • St. Paul, MN 55104 • (651) 647-9009 • www.immunize.org

Herpes Zoster (HZ Shingles) vaccine

Purpose: To reduce morbidity and mortality from herpes zoster shingles infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of herpes zoster shingle vaccination based on meeting the following criteria:
   Any adult 60 years of age or older who has had a case of chicken-pox or received the chicken-pox vaccine previously

2. Screen all patients for contraindications and precautions to shingles vaccine:
   a. **Contraindications:**
   - Are < 60 years of age
   - Serious life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of the HZ shingles vaccine. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf
   - Pregnant now, or may become pregnant with in three months of receiving the shingles vaccine
   - History of primary or acquired immune deficiency including HIV/AIDS, leukemia, lymphomas of any type, and other malignant neoplasms affecting the bone marrow or lymphatic system
   - Are on immune suppressive therapy including high dose corticosteroids
   - Have active untreated tuberculosis

   b. **Possible adverse reactions:** redness, pain, swelling, itching, warmth, bruising at the injection site, and headache.

3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record of office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis

4. Administer 0.65mL of Zostavax given SC (23-25g, 5/8-3/4" needle) for 1 dose only.

5. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

7. Report all adverse reactions to shingles vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Updated 11/19/06

Human Papillomavirus Virus (HPV) Vaccine

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adolescents and adults in need of HPV vaccination based on meeting any of the following criteria:
   a. females 11-12 years of age (females 9 years of age may also be considered for the vaccine)
   b. females 13-26 years of age who have not been vaccinated previously or who have not completed the full vaccine series

2. Screen all patients for contraindications and precautions to HPV vaccine:
   a. **Contraindications:**
      - Serious life-threatening allergic reaction to yeast, or after receiving a previous dose of HPV vaccine, or any other component of HPV vaccine. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf
      - Avoid use in pregnancy
        -If a woman is found to be pregnant after the series is initiated, the remaining doses should be delayed until after completion of the pregnancy.
        -Merck maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to Gardasil®. Patients and health care providers are encouraged to report any exposure to Gardasil® during pregnancy by calling 800-986-8999
      - Consider postponing vaccination in persons with moderate or severe illness, with or without fever, until recovery, to minimize potential adverse effects. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.
   b. **Precautions:** moderate to severe fever and pain, redness, or tenderness at the injection site

3. Provide all patients with a copy of the most current federal Vaccine information Statement (VIS). You must document, in the patient's medical record of office log, the publication date of the VIS and the date it was given to the patient. Provide on-English speakers with the VIS in their native language if available; these can be found at www.immunize.org/vis

4. For persons 9-26 years of age, administer 0.5mL per dose given IM (22-25g, 1-1 1/2" needle) in the deltoid region of the upper arm or higher anterolateral areas of the thigh.

5. Provide subsequent doses of HPV vaccine to complete each patient's 3 dose schedule by observing a minimum interval of 2 months for the second dose, and 6 months for the third dose.

6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal Immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

8. Report all adverse reactions to HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

Updated 11/19/2006

Influenza Vaccine

Purpose: To reduce morbidity and mortality from influenza by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure:

1. Identify adults in need of influenza vaccination based on meeting any of the following criteria:
   a. Age 50 years or older
   b. Having any of the following conditions:
      - chronic disorder of the pulmonary or cardiovascular system, including asthma
      - chronic metabolic disease (e.g., diabetes), renal dysfunction, hemoglobinopathy, or immunosuppression (e.g., caused by medications, HIV) that has required regular medical follow-up or hospitalization during the preceding year)
      - any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, seizure disorder or other neuromuscular disorder)
      - will be pregnant during the influenza season
   c. Residence in a nursing home or other chronic-care facility that houses persons of any age who have chronic medical conditions
   d. In an occupation or living situation that puts one in proximity to persons at high risk, including
      - a healthcare worker, caregiver, or household member in contact with person(s) at high risk of developing complications from influenza
      - a household contact or out-of-home caretaker of a child age 0–59 months
   e. Wish to reduce the likelihood of becoming ill with influenza

2. Screen all patients for contraindications and precautions to influenza vaccine:
   a. **Contraindications:** serious reaction (e.g., anaphylaxis) after ingesting eggs or after receiving a previous dose of influenza vaccine or an influenza vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf. Do not give live attenuated influenza vaccine (LAIV) to pregnant women, immunosuppressed persons, or persons who have a history of Guillain-Barré syndrome. Use of inactivated influenza vaccine is preferred over LAIV for close contacts of severely immunosuppressed persons during periods when the immunocompromised person requires a protective environment.
   b. **Precautions:** moderate or severe acute illness with or without fever

3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.

4. Administer 0.5 mL of injectable trivalent inactivated influenza vaccine (TIV) IM (22–25g, 1–1½" needle) in the deltoid muscle. Alternatively, healthy persons ages 5–49 years without contraindications may be given 0.5 mL of intranasal LAIV; 0.25 mL is sprayed into each nostril while the patient is in an upright position.

5. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.

6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

7. Report all adverse reactions to influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

www.immunize.org/catg.d/p3074.pdf • Item #P3074 (8/06)

Measles, Mumps, & Rubella Vaccine

Purpose: To reduce morbidity and mortality from measles, mumps, and rubella by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of initial vaccination against measles, mumps, or rubella who were born in 1957 or later with no history of receipt of live, measles-, mumps-, and/or rubella-containing vaccine given at 12 months of age or older or other acceptable evidence of immunity (e.g., laboratory evidence). Combination MMR vaccine is recommended if one or more component is indicated.
2. Identify adults born in 1957 or later in need of a second dose of measles, mumps, and rubella (MMR) vaccine who are either planning to travel internationally, a student in a college, university, technical or vocational school, or a health care worker.
3. Screen all patients for contraindications and precautions to measles, mumps, and rubella (MMR) vaccine:
   a. **Contraindications:**
      - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of MMR vaccine or to an MMR vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
      - pregnant now or may become pregnant within 1 month
      - known severe immunodeficiency (e.g., hematologic and solid tumors; congenital immunodeficiency; long-term immunosuppressive therapy, or severely symptomatic HIV infection)
   b. **Precautions:**
      - recent (<11 months) receipt of antibody-containing blood product (specific interval depends on product)
      - history of thrombocytopenia or thrombocytopenic purpura
      - moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language; these can be found at www.immunize.org/vis
5. Administer 0.5 mL MMR vaccine SC (23–25g, 5/8–3/4" needle) in the posterolateral section of the upper arm.
6. For adults in need of second doses of MMR, observe a minimum interval of 4 weeks between the first and second doses.
7. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
8. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
9. Report all adverse reactions to MMR vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the_____ clinic until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____

www.immunize.org/catg.d/p3079pdf • Item #P3079 (12/03)

Meningococcal Vaccine

Purpose: To reduce morbidity and mortality from meningococcal disease by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination against meningococcal disease based on any of the following criteria:
   a. anticipated college enrollment, particularly anticipated residence in an on-campus dormitory
   b. anticipated travel to a country in the "meningitis belt" of sub-Saharan Africa or other location of epidemic meningococcal disease, particularly if contact with the local population will be prolonged
   c. anticipated travel to Mecca, Saudi Arabia, for the annual Hajj
   d. diagnosis of a damaged spleen; splenectomy
   e. diagnosis of terminal complement component deficiency (an immune system disorder)
   f. employment as a microbiologist with routine exposure to isolates of *N. meningitidis*
   g. military recruits
   h. any other adult wishing to decrease their risk for meningococcal disease
   i. age 55 years or younger with history of receiving **meningococcal polysaccharide vaccine (MPSV4)** at least 5 years earlier and with continued risk for infection (e.g., living in epidemic disease areas).
2. Screen all patients for contraindications and precautions to meningococcal vaccine:
   a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of meningococcal vaccine or to a meningococcal vaccine component, including diphtheria toxoid for **meningococcal conjugate vaccine (MCV4)**. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
   b. **Precautions:** moderate or severe acute illness with or without fever
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. For adults ages 55 years and younger, administer 0.5 mL MCV4 via the intramuscular route (22–25g, 1–1½" needle) in the deltoid muscle. If MCV4 is unavailable, MPSV4 is an acceptable alternative, although it must be given subcutaneously. For adults older than age 55 years, administer 0.5 mL MPSV4 via the subcutaneous route (23–25g, ⅝" needle) in the posterolateral fat of the upper arm.
5. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
6. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
7. Report all adverse reactions to meningococcal vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

www.immunize.org/catg.d/p3081.pdf • Item #P3081 (5/06)

Pneumococcal Vaccine - Adults

Purpose: To reduce morbidity and mortality from pneumococcal disease by vaccinating all patients who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Procedure

1. Identify adults in need of vaccination with pneumococcal polysaccharide vaccine (PPV) based on the following criteria:
   a. Age 65 years or older with no or unknown history of prior receipt of PPV
   b. Age 18–64 years with no or unknown history of prior receipt of PPV and any of the following conditions:
      i. chronic cardiovascular disease (e.g., congestive heart failure, cardiomyopathies)
      ii. chronic pulmonary disease (e.g., emphysema or chronic obstructive pulmonary disease [not asthma])
      iii. diabetes mellitus, alcoholism, chronic liver disease (cirrhosis), or cerebrospinal fluid leaks
      iv. functional or anatomic asplenia (e.g., sickle cell disease, splenectomy)
      v. immunosuppressive conditions (e.g., HIV infection, leukemia, congenital immunodeficiency, Hodgkin's disease, lymphoma, multiple myeloma, generalized malignancy)
      vi. immunosuppressive chemotherapy (e.g., alkylating agents, antimetabolites, long-term systemic corticosteroids)
      vii. organ or bone marrow transplantation
      viii. chronic renal failure or nephrotic syndrome
      ix. candidate for or recipient of cochlear implant
2. Identify adults in need of a second and final dose of PPV if five or more years have elapsed since the previous vaccination and the patient is:
   a. Age 65 years or older and received prior PPV vaccination when less than age 65 years
   b. At highest risk for serious pneumococcal infection and/or likely to have a rapid decline in pneumococcal antibody levels (i.e., categories iv.-viii. above)
3. Screen all patients for contraindications and precautions to PPV vaccine.
   a. **Contraindications:** a history of a serious reaction (e.g., anaphylaxis) after a previous dose of PPV or to a vaccine component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/a/excipient.pdf
   b. **Precautions:** a moderate or severe acute illness with or without fever
4. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Although not required by federal law, it is prudent to document in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available. These can be found at www.immunize.org/vis
5. Administer 0.5 mL PPV vaccine either IM (22–25g, 1–2" needle) or SC (23–25g, 5/8–3/4" needle).
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to PPV to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.org or by calling (800) 822-7967. VAERS report forms are available at www.vaers.org

This policy and procedure shall remain in effect for all patients of the_____ clinic until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____

Standing Orders for Administering Tetanus-Diphtheria Toxoids & Pertussis Vaccine (Td/Tdap) to Adults

Purpose: To reduce morbidity and mortality from tetanus, diphtheria, and (where indicated) pertussis by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses may vaccinate adults who meet the criteria below.

Procedure

1. Identify adults in need of vaccination against tetanus, diphtheria, and (where indicated) pertussis based on the following criteria:
   a. lack of documentation of at least 3 doses of tetanus- and diphtheria-containing toxoids
   b. younger than age 65 years with no history of pertussis-containing vaccine given since age 10 years
   c. completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with receipt of the last dose being 10 years ago or longer
   d. recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years
2. Screen all patients for contraindications and precautions to tetanus and diphtheria toxoids (Td) and, if applicable, pertussis vaccine (Tdap):
   a. **Contraindications:**
      - a history of a serious reaction (e.g., anaphylaxis) after a previous dose of Td or to a Td or Tdap component. For a list of vaccine components, go to www.cdc.gov/nip/publications/pink/appendices/b/excipient-table-2.pdf.
      - for Tdap only, a history of encephalopathy within 7 days following DTP/DTaP given before age 7 years
   b. **Precautions:**
      - history of Guillain-Barré syndrome within 6 weeks of previous dose of tetanus toxoid-containing vaccine
      - an unstable neurologic condition
      - moderate or severe acute illness with or without fever

      Note: Use of Td or Tdap is not contraindicated in pregnancy. At the provider's discretion, either vaccine may be administered during the 2nd or 3rd trimester.
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available; these can be found at www.immunize.org/vis.
4. Administer 0.5 mL Td (or Tdap, if appropriate) vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle.
5. Provide subsequent doses of Td (a one-time dose of Tdap may be substituted for Td if younger than 65 years) to adults as follows:
   a. to complete the primary 3-dose schedule: observe a minimum interval of 4 weeks between the first and second doses, and 6 months between the second and third doses.
   b. to boost after primary schedule is complete: observe a 10-year interval since previous dose of Td/Tdap; if protection against pertussis is needed, an interval of 5 years is recommended and intervals as short as 2 years or less can be observed for parents and caregivers of infants younger than age 12 months, healthcare workers having direct patient contact, and adults in a pertussis outbreak setting.
   c. In pregnancy, when indicated, give Td or Tdap in 2nd or 3rd trimester. If not administered during pregnancy, give Tdap in immediate postpartum period.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not given, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.
8. Report all adverse reactions to Td and Tdap vaccines to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

www.immunize.org/catg.d/p3078.pdf • Item #P3078 (9/06)

Pharmacy Name
Address 1
Address 2
Phone#

Patient Name:_____
DOB:_____
Today's Date:_____

VACCINE ADMINISTRATION RECORD, SCREENING and PATIENT CONSENT

		YES	NO
1.	Have you ever had a severe reaction to any vaccine that required medical care?	_____	_____
	If yes, describe:_____		
2.	Do you have any allergies to food, medications, or vaccines?	_____	_____
3.	Are you sick today?	_____	_____
4.	Have you had Guillain-Barre Syndrome, seizure, brain, or nerve problems?	_____	_____
5.	Are you pregnant or planning to become pregnant in the next 3 months?	_____	_____
6.	Are you or anyone in your household being treated with chemotherapy or radiation for cancer, have HIV/AIDS or any immune deficiency disorder?	_____	_____
7.	Do you or anyone in your household take oral prednisone (>20mg/day) or other oral steroids, or anticancer drugs?	_____	_____
8.	Do you have a bleeding disorder or take "blood thinners" like coumadin or heparin?	_____	_____

The following questions will help determine any other indications or contraindications

1. What adult vaccinations has this patient received (vaccine and date)?

   _____

   _____

2. List all Rx and OTC medications this patient is currently taking

   _____

   _____

3. List all current medical conditions

   _____

   _____

INFORMATION ABOUT PERSON TO RECEIVE VACCINE (please print)

NAME last	first	middle initial	SOCIAL SECURITY NUMBER
ADDRESS	CITY	STATE/ZIP	PHONE#
BIRTHDATE	SEX	PHYSICIAN	PHYSICIAN PHONE OR FAX

☐ **Yes** ☐ **No** I request to have this information sent to the physician's office specified above

DO NOT WRITE BELOW THIS LINE - For Pharmacy Use Only

VACCINE	LOT #	EXP DATE	MANUFACTURER	DOSE (mL)	ADMINISTRATOR	VIS DATE

Please read the following statements and sign below on the signature line.
I have read or have had explained the information provided about the vaccine I am to receive. I have had a chance to ask questions that were answered to my satisfaction. I believe I understand the benefits and risks of vaccination and ask that the vaccine be given to me or to the person named above for whom I am authorized to make this request.
Medicare, I do hereby authorize the <*Pharmacy*> to release information and request payment. I certify that the information given by me in applying for payment under Medicare is correct. I authorize release of all records to act on this request. I request that payment of authorized benefits be made on my behalf.

X _____ DATE: _____
Signature of person to receive vaccine or person authorized to make the request (parent or guardian)

APPENDIX E

University of Southern California
USC Medical Plaza Pharmacy
1510 San Pablo Street, #144 Los Angeles, CA 90033
(323) 442-8411

Facsimile Transmittal

To:	Fax: ( ) -
From:	Date: / /
Re: Patient Name	Pt. DOB:
CC:	Pages:

This fax has been sent to you with the consent of your patient to notify you that the patient named above received the following vaccination(s) at our pharmacy on the date that is listed below. Please make a note of this in the patient's chart and feel free to call at the number above with any questions.

Administration Date	Product	Dose	Comments

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

(continued on page 2)

Technical content reviewed by the Centers for Disease Control and Prevention, Nov. 2006.

www.immunize.org/catg.d/p3082.pdf • Item #P3082 (11/06)

(continued from page 1)

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

Supplies Needed

- ☐ Aqueous epinephrine 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen). If EpiPens are stocked, at least three adult EpiPens (0.30 mg) should be available.
- ☐ Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and 25 mg or 50 mg capsules or tablets and syrup (12.5 mg/5 mL suspension)
- ☐ Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)
- ☐ Wristwatch with second hand
- ☐ Adult airways (small, medium, and large)
- ☐ Sphygmomanometer (adult and extra-large cuffs) and stethoscope
- ☐ Adult size pocket mask with one-way valve
- ☐ Alcohol swabs
- ☐ Tourniquet
- ☐ Tongue depressors
- ☐ Flashlight with extra batteries (for examination of the mouth and throat)
- ☐ Cell phone or access to an on-site phone

Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

Treatment in Adults

a. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

b. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.

c. Administer aqueous epinephrine 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).

d. In addition, for systemic anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1–2 mg/kg, up to 100 mg maximum single dose.

e. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

f. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.

g. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.

h. Notify the patient's primary care physician.

Sources: 1. American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases.* 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006:64–66.
2. American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery,* 2002.
3. *Got Your Shots? A Providers Guide to Immunizations in Minnesota,* Second Edition, Minnesota Department of Health, 2001:80-82.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the _____ (*name of clinic*) until rescinded or until _____ (*date*).

_____ Medical Director's signature

_____ Effective date

Agenda Item 7

Competency Committee Update

State of California Department of Consumer Affairs

Memorandum

To: **Licensing Committee** **Date: May 23, 2007**

From: **Board of Pharmacy**

Subject: **Competency Committee Report**

On June 1, the board will have a new test administrator for the CPJE. At the time of this writing, there is not much information to share about the transition.

I hope to be able to provide the new CPJE Candidate Handbooks at our meeting. This handbook contains information about how to schedule an exam and where the examination centers are located. However, the handbooks have not yet been finalized or released for distribution.

Meanwhile, in a two-week period in April, the board qualified over 400 2007 graduates from California schools, many of whom wanted to take the examination from the current vendor, Thompson Prometric. This contract will end on May 31, 2007. I cannot advise at this point how many of them actually scheduled and took the exam. Staff worked hard with the California schools to make this happen.

National Association of Boards of Pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
Tel: 847/391-4400 • Fax: 847/391-4501
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director

DATE: May 10, 2007

RE: NABP Selects New Test Vendor for NAPLEX and MPJE

Beginning January 2, 2008, NABP will utilize Pearson VUE as the test vendor for the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE). After thorough analysis and review of the capabilities of test vendors, it was found that utilizing the services of Pearson VUE would be in the best interests of the candidates, the state boards of pharmacy, and NABP. As such, the Advisory Committee on Examinations recommended, and the NABP Executive Committee approved, the transition of the examinations to Pearson VUE.

NABP is working with Pearson VUE and the current examination vendor, Thomson Prometric, to minimize the impact of the transition on the candidates and the boards of pharmacy. NABP thanks Thomson Prometric for the service it has provided over the years and looks forward to continuing a relationship with the company as other opportunities become available within the Association.

Pearson VUE is the global leader in electronic testing services for academic admissions, certification, and licensure programs. Pearson VUE offers examinations through the world's largest network of test centers in 151 countries, providing testing services for information technology, regulatory and certification boards, academic, government, and corporate clients. Pearson acquired Promissor in January 2006, extending its leadership in the testing and certification industry. Promissor has delivered the Pre-NAPLEX and the Pre-FPGEE via the Internet since May 2003.

More information regarding the change from Thomson Prometric to Pearson VUE will be communicated as NABP moves forward with this transition

If you have any questions, please contact me via e-mail at mdickson@nabp.net or via phone at 847/391-4400 or 1-800/774-6227. Thank you.

cc: NABP Executive Committee
Advisory Committee on Examinations
Carmen A. Catizone, Executive Director/Secretary